MEETING

STATE OF CALIFORNIA

OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT

ENVIRONMENTAL CONTAMINANT BIOMONITORING PROGRAM

SCIENTIFIC GUIDANCE PANEL

ELIHU HARRIS BUILDING

AUDITORIUM

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OAKLAND, CALIFORNIA

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10:05 A.M.

JAMES F. PETERS, CSR, RPR
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APPEARANCES

PANEL MEMBERS

Ulrike Luderer, Chairperson, M.D., Ph.D.

Dwight Culver, M.D.

Marion Kavanaugh-Lynch, M.D., M.P.H.

Thomas McKone, Ph.D.

Gina Solomon, M.D., M.P.H.

Michael Wilson, Ph.D., M.P.H.

OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT

Dr. George Alexeeff, Acting Director

Ms. Carol Monahan-Cummings, Chief Counsel

Ms. Amy Dunn, Safer Alternative Assessment and Biomonitoring Section

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

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

Dr. Laurel Plummer, Associate Toxicologist, Safer Alternatives Assessment and Biomonitoring Section

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

DEPARTMENT OF PUBLIC HEALTH

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

Dr. Laura Fenster, Environmental Health Investigations Branch

Dr. Jianwen She, Chief, Biochemistry Section

APPEARANCES CONTINUED

DEPARTMENT OF TOXIC SUBSTANCES CONTROL

Dr. Myrto Petreas, Chief, Environmental Chemistry Branch

ALSO PRESENT

Ms. Nancy Buermeyer, Breast Cancer Fund

Ms. Trudy Fisher

Ms. Diana Graham

Ms. Sharyle Patton, Commonweal

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PROCEEDINGS

OEHHA ACTING DIRECTOR ALEXEEFF: Good morning, everyone. I'm George Alexeeff, Acting Director of the Office of Environmental Health Hazard Assessment. I want to welcome the Panel and the public and the staff to our meeting of the Scientific Guidance Panel for Biomonitoring California. I want to thank the Panel members who have taken time out of their busy schedules to be with us today, and to advise us on this very important program.

I have a couple of announcements on logistics. In terms of restrooms, out this back door, either of these two doors, and to your right, when you go out the door. Also, I want to note the emergency exits that we have, either out the front or out the back.

This meeting is being videotaped, so I would like everyone to, if they're making a comment, to speak into the mic so everyone can hear it, both now and later on. And this meeting is also being transcribed.

We're sorry we can't webcast this meeting, but the logistics for that in this particular building are difficult. We will be posting the transcript of the meeting probably about a month after this meeting. So again, speak clearly into the microphones.

So I'll give a little overview of last meeting. The last Scientific Guidance Panel meeting occurred on --

it was in Sacramento on November 10th in last year 2011. And at that meeting, the Panel received updates of the program, the laboratory progress and activities, and provided input. Also, we heard presentations from the Center for Disease Control, CDC, and the Washington and New York State Biomonitoring Programs. And we discussed the issues that were of common interest to the federal and State Biomonitoring Programs.

We also received an update from the Maternal and Infant Environmental Exposure Project, referred to as MIEEP from our UCSF partners. And we heard the results of the Program's usability testing on the results return materials for the Firefighter Occupational Exposure Project, we call FOX, and the Panel provided input.

So if you would like a summary of the meeting highlights, and the Panel's input to the program, it's now been posted, so you can see it on our website, biomonitoring.ca.gov.

So I would now like to turn the meeting over to the chair of the Scientific Guidance Panel, Dr. Luderer.

CHAIRPERSON LUDERER: Thank you, Dr. Alexeeff. I'd also like to welcome everyone, all the members of the public who are here, the Panel members and the Program staff. Welcome to our meeting. I wanted to just first go over the various goals that we have for the Panel for the

meeting today.

We're going to receive program and laboratory updates and provide input on those. We're going to learn about and provide feedback on the initial results from Biomonitoring California collaborations and respond to specific questions about the program's upcoming data summary report that's projected to be completed in July of this year.

We are also going to consider non-halogenated aromatic phosphates as potential designated chemicals. We'll discuss a preliminary screen of bisphenol A substitutes and structurally related compounds as possible candidates for future consideration as potential designated chemicals, and provide input on next steps for that. And we'll also provide other input on chemical selection planning.

So as usual, each presentation will be followed by an opportunity for panel questions, a public comment period, and then time for further Panel discussion and recommendations.

So I wanted to go over the handling of public comment. It's a little different today because we're not webcasting. So if a member of the public would like to make a comment, he or she should fill out a comment card, which can be obtained from the staff table outside the

room, and then you can turn the cards into Amy Dunn -- Amy is waving her hand up there with the cards.

So to ensure that the meeting proceeds on schedule, and that all commenters have the opportunity to speak, we'll time the public comments, and they will be subject to time limits. So the time allotted will be divided equally among all the individuals who wish to speak during that comment period.

So please do keep your comments focused on the agenda topics being presented. And there will also be an open public comment period at the very -- as the last item of the day, at which any topic can be addressed.

I also wanted to again remind everyone to speak directly into the microphone and please introduce yourself before speaking. This is for the benefit of both the transcriber and the videographer.

So the materials for the meeting have been provided to Scientific Guidance Panel members, and are also available on the website to the public. And there are also some handouts and a sample of the Panel's folder at the staff table outside the auditorium.

We'll take two breaks today, one for lunch around 12 noon, and one in the afternoon.

And so, now, it gives me great pleasure to announce the first agenda item, which is an update on

Biomonitoring California Program Activities and this will be presented by Dr. Rupali Das who is the Chief of the Exposure Assessment Section, California Department of Public Health, and is the lead of Biomonitoring California.

Dr. Das.

(Thereupon an overhead presentation was presented as follows.)

DR. DAS: Thank you, Dr. Luderer. Welcome to the Panel members and members of the audience. It's my pleasure to provide you an update of the program accomplishments over the last several months, since our last Panel meeting.

After my presentation, I'll be followed by Dr. Jianwen She and Dr. Myrto Petreas, who will provide more details on the laboratory updates.

Excuse me, we're adjusting the light.

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DR. DAS: I'll be providing an update on staffing changes. Progress that's being made on three major projects: The Maternal and Infant Environmental Exposure Project, or MIEEP, the Firefighter Occupational Exposures projects, or FOX, and the Biomonitoring Exposures Study or BEST. We like acronyms in this program.

I'll be describing a few additional activities

and then briefly describing what we plan to do in the upcoming months.

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DR. DAS: This slide shows the staff changes. Other people who follow me will be telling a little bit more about the staff. But overall, we've had five new people join our program, and one position, the Environmental Laboratory Scientist, remains unfilled, and we're working to fill that.

I want to tell you a little bit more about Duyen Kauffman, our results return coordinator. The other staff listed on this slide are either staff in the laboratory or in OEHHA. And other people who present will be talking to you more about those staff.

Duyen Kauffman joined us a few months ago. And I'd like to have her stand up and wave.

(Applause.)

DR. DAS: Duyen entered the field of public health after studying languages for many years. Her public health experience includes community development work in Vietnam, and working with Vietnamese and Hispanic communities at county clinics in Marin with a focus on women's health. She is a project coordinator focused on individual results return. And we're very happy to have her with us.

Next, I'd like to provide you an update on the MIEEP, also known as the Chemicals in Our Bodies Project.

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DR. DAS: Just to remind you, MIEEP is a collaboration with UCSF, where the PI there is Dr. Tracey Woodruff, and UC Berkeley, the PI there is Dr. Rachel Morello-Frosch. The population that we are studying as part of MIEEP is gathered as a convenience sample recruited from the San Francisco General Hospital, labor and delivery clinic.

We have completed recruitment and enrollment. There were 92 mothers enrolled, and 65 mother-infant pairs. I'll describe a little bit more detail about what we've done, and sample analyses. Some of them have been completed. Some of them are ongoing, and we are preparing to return the first set of results to the participants.

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DR. DAS: This slide shows the analyses, either completed or in the process of being completed or in progress. You'll see that we've completed the analysis of metals in blood, perfluorinated compounds or PFCs, polybrominated diphenyl ethers, or PBDEs, polychlorinated biphenyls, PCBs, organochlorine pesticides, selected brominated flame retardants. And we are in the process of reviewing phthalates and metabolites of pyrethroid and

organophosphate pesticides, as well as bisphenol A and triclosan. We're currently in the process of analyzing metals in urine and the hydroxylated polycyclic aromatic hydrocarbons.

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DR. DAS: This slide shows where we were at the last Panel meeting. We showed this slide last time. The check marks depict the steps in the project that have been completed and the gray box shows what we're in the process of doing -- what we were in the process of doing at the last meeting.

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DR. DAS: Since the last meeting, we've completed the analysis of the first set of chemicals. We have completed also the abstraction and entry of the medical records and the questionnaire data, and the translation of the materials that will be returned to participants into Spanish. And we're in the process of analyzing data and getting everything ready to return the results to the participants.

As you'll recall, the Program is required to return results to participants who wish to receive those results.

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DR. DAS: In addition to returning the results to

participants, we are planning to evaluate some aspects of the results return. This is being done in collaboration with Dr. Rachel Morello-Frosch at the UC Berkeley School of Public Health, and is being done in two phases.

The first phase will assess the understanding of the participants -- their reaction to the first set of results, which will be returned shortly, and that will inform our future results return efforts.

And after all the results have been returned to participants, there will be another phase of evaluation to assess the understanding of participants and their reaction to the results return. And these efforts are being funded by a variety of sources, State funding as well as grants from Wellness and other sources as well.

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DR. DAS: At the last meeting, I had presented the one case that had an elevated blood mercury level, and had described how the program in collaboration with the County and U.S. EPA had done a home investigation and identified the source of the elevated mercury as a cream, facial cream, that was brought in from Mexico in personal luggage, and had been contaminated with mercury.

After that incident, and as a result of other cases that we've investigated in California, we worked with other organizations to increase awareness and see

what we could do to prevent more cases of mercury toxicity, as a result of use of facial creams, which we believe is more widespread than we were actually able to detect.

We were successful in involving U.S. FDA. Our collaboration with them began last fall. And I'm really happy to say that as a result of involving them, they issued a mercury consumer alert that came out last week, and it was broadcast nationally, alerting consumers to the dangers of skin products that contain mercury and can result in inorganic mercury toxicity. So I would count this as a public health success of the Program.

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DR. DAS: Next, I'd like to provide you with an update on the Biomonitoring Exposures Study or BEST. This is a collaboration with Kaiser Permanente Northern California Division of Research. And to remind you, this is -- unlike the MIEEP study, which I described, this is a stratified random sample of adult Kaiser members who live in the Central Valley. The catchment area is the blue area shown on that map. There are seven counties in that Central Valley area from which we're recruiting participants.

Our goal for the pilot is to recruit 100 participants and we are almost there. We're currently

continuing to recruit, enroll, and collect samples.

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DR. DAS: At the last meeting, we had completed the selection of eligible participants, and we are in the process of scheduling home visits, consenting and enrolling participants and collecting samples and questionnaires. And we are continuing to do those things. In addition, we are entering data and analyzing samples for blood metals.

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DR. DAS: Since the last meeting, we have made the decision to expand this stratified random sample to an additional 200 participants. These new participants will be both English and Spanish speaking. Whereas, the previous study that I described, the pilot, recruited only English speaking participants. The expanded study will recruit Spanish speaking participants, in addition to English speaking participants.

And all the materials, for example the questionnaire, the results return materials and consent and everything will be developed and is being developed in both Spanish and English. These materials are currently under the review of the IRBs, both within the Department of Public Health and Kaiser.

Just show you the expanded BEST study.

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DR. DAS: This slide describes the changes and the advantages of the expanded BEST. In addition to recruiting participants in Spanish, the expanded BEST will offer the participant the choice of filling out the consent and the questionnaire electronically. And they'll be able to access this through a secure web log-in through their Kaiser member I.D.

And it will also allow us to generate a lab -- a requisition and lab collection electronically, so the participants can choose to go to a Kaiser lab of their choice and at their convenience. So we won't have to arrange a home visit to collect the samples or to collect the questionnaires.

Participants will have the choice to fill out a hard copy questionnaire or consent, if they choose, but they will also have the choices to do this all electronically.

The samples will all be collected at Kaiser labs. We will not give them the choice to collect samples at their homes.

These modifications offer a number of advantages. Not only are we recruiting participants who represent the Central Valley, but we're also capturing different languages spoken. We're also able to expedite participant

enrollment. They have the ability to fill out the questionnaire and consent at their convenience. And this will result in reduced costs to the Program. The cost of sending a phlebotomist or interviewer to the home is saved by allowing the participant to fill these materials out electronically, and they can do so at their convenience, and can go to the labs to have the samples collected at their convenience.

We feel that this offers a number of advantages and is a really good model for sustainability for the Program's future.

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DR. DAS: Next, I'd like to describe the FOX project. And I'm sure you do have questions, and there will be an opportunity to ask questions after I'm done presenting this next portion.

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DR. DAS: The FOX project is a collaboration with the University of California, Irvine and the Orange County Fire Authority. This is a convenience sample, just like MIEEP.

We recruited 101 Orange County Fire Authority firefighters at the time of their wellness and fitness exams, which took place at the UC Irvine Center for Occupational Environmental Health Clinic.

We have returned the first set of results, and I'll describe the materials that we used to return these results, that consisted of blood metals and the perfluorinated compounds. We've completed the collection of checklists for each firehouse from which participants were recruited and we continued to analyze lab data.

Another thing that we did that was not part of the Biomonitoring California project was to collect dust at a subset of the firehouses. And that analysis is ongoing as well.

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DR. DAS: So at the last meeting, we had completed the recruitment of participants, enrollment, and we were in the process of analyzing chemicals, and getting ready to return results.

And, at this point, we've completed the analysis of the first set of chemicals and have returned the results.

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DR. DAS: And I'd like to go over the results return packet with you in a little bit of detail. At the last meeting, you heard from Dr. Sandy McNeel and Amiko Mayeno, our health educator, about the process that we went through to develop these results return materials.

We conducted a process known as usability

testing, where staff went down to the UC Irvine clinic and tested materials on firefighter participants, got their feedback, and modified the materials based on their feedback.

Not all the firefighters who provided feedback were ones who had donated samples; a subset of those, in whom we tested the materials were participants in the project. The packet that they received in January consisted of the following materials.

And I want to say that this results return package is something that we feel is a significant achievement of the Program. This is first time the Program has returned results to participants. It is, I feel, highly understandable, and it took a great amount of work to generate this simple set of materials. Simplicity is not easy, and this was the product of hard work on the part of a lot of people. The process was led by Amiko Mayeno. And so I want to acknowledge her efforts.

(Applause.)

DR. DAS: But staff from the entire program were involved, including staff from OEHHA and other staff as well. So everybody really deserves a big round of applause for that.

The packets that you have in your hands, Panel members have in their hands, and I believe there's a copy

available to look at in the -- outside on the desk, and it's also available on the website, consists of the following materials:

A cover letter; a fact sheet that is focused on the firefighters and describes why we studied firefighters; and the mock chemical results for each set of analytes that were returned to the firefighters. And it's mock, because this is an example of the individual results return packet. There's no individual level -- actual individual level results in here. And the group data, the data that is meant to represent the FOX group is also not real. The NHANES data that is in this packet is real.

The participants who received the packages, of course, did receive the actual data. I'll be going over each individual component of this next.

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DR. DAS: The FOX fact sheet describes for firefighters why we chose that group to study. And this was developed because firefighters wanted to know why they were being studied, and how they played a role in the entire Biomonitoring California project. This described why we studied them, what we can learn from studying this group, and provided some positive messages for firefighters.

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DR. DAS: We have a section that presents results for the metals that were analyzed as part of FOX, the blood metals, lead, mercury, cadmium, and manganese. We have a brief description of -- a one to two sentence description of the metal, where it is found in the environment, the test results, the individual results, the range within the study, and the national levels, the data from NHANES, the median, the 95th percentile. And if there is a level of concern for the particular compound, that is presented as well.

The packet that you have is the packet that was returned to the male firefighters. Women have a different level of concern, and so women who received their package got a different set of comparison data.

And the narrative describes a little bit more about the table that -- the table is presented for people who like to receive the data in tabular format. The narrative then describes a little bit more about that data and how the results can be compared to other data.

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DR. DAS: The perfluorinated chemicals, PFCs, are presented in a slightly different format. We did not -- because there are so many PFCs, 12 PFCs, that were analyzed, we put all of them in one table. And unlike the

metals, there aren't levels of concern for the PFC's, and so we felt it would be best to present all the data, but to put them all in one table. So the PFC table looks a little bit different than the metals table.

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DR. DAS: There's a national level, a median and a 95th percentile, but no level of concern in the PFC table.

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DR. DAS: After the data, there are the FAQs, the frequently asked questions. This is just an example from mercury. The FAQ sheet describes where mercury is found, the known effects on people's health, and what can be done to reduce exposure to mercury, as well as websites the person can go to to get more information.

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DR. DAS: Similarly, we have information for the PFCs.

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DR. DAS: After the frequently asked questions, we have graphical depiction of the results for your packet. Again, these are mock results not real. And on this slide, I'm presenting an example of a PFC and a metal. On your left, there's a graphical representation of PFOA, one of the PFCs, and it contains the individual's

level and the level within FOX, as well as the national level, but no level of concern. Again, because there isn't any for the PFCs, for the heavy metals where there are levels of concern, we present that in graphical format as well.

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DR. DAS: And at this point, I would like to answer any questions you may have either on the FOX results return material or anything else I've spoken about so far.

CHAIRPERSON LUDERER: Are there any questions from any Panel members?

PANEL MEMBER SOLOMON: Yes. This is Gina Solomon. Fantastic presentation. Very impressive progress since the last meeting. So I must say I'm very impressed.

I have actually a number of questions. A couple are around the expanded BEST study. Two things about the questionnaire. One is how would participants who don't have easy, you know, Internet access obtain a paper copy of the questionnaire and return it? What's the mechanism for doing that?

And then the other is, is there a way to access the questionnaire and fill it out on a smart phone or other mobile device, instead of on a computer, because I

think that might be more -- might be easier for some people.

DR. DAS: Thank you, Dr. Solomon for acknowledging our efforts on the materials. In answer to your questions the participants can choose to fill out materials in hard copy, basically by -- it's built into the recruitment process. We initially -- once the eligible participants are selected, they're sent a postcard. And they're asked to return it if they don't want to participant or if they have a specific request. So if they send the postcard back and request to be contacted or to participate in hard copy, we would do that. If they don't respond, we then contact them. And then during that process, they can either choose not to participate or they can choose to participate in and fill out the materials in hard copy.

So that's basically the process that occurs. They're contacted in some way and indicate a preference to fill out the materials in hard copy. With regards to question about the ability to fill out these materials on a smart phone, that's an excellent idea. And that's definitely something we will take away.

At this point, it's not an option because of the security concerns. And so we haven't explored that. But as the Program moves forward, I think that's definitely

something that we should think about. So we'll definitely -- we'll consider that.

I should mention that it's Kaiser staff who are developing the electronic questionnaire and putting in considerable in-kind efforts to do that. So we will -- some of the restrictions on the ability to fill out the questionnaire electronically will depend on what their IRB and their system allows us to do, but we'll definitely take that suggestion back.

CHAIRPERSON LUDERER: Dr. Wilson.

PANEL MEMBER WILSON: Thank you. I just want to second Gina's remarks about, I think, the materials particularly -- as you said, the FOX translation materials are excellent. They're, you know, just very readable, just transparent. And I just had a couple questions on -- one is on the FOX packet, if there's -- if you're contemplating in the frequently asked questions section or somewhere in the beginning that describes in fairly, you know, clear language, simple language what the 95th percentile is, what micrograms per liter means -- or, I think it's -- yeah, micrograms per liter, the median, just for interpretation.

DR. DAS: Yes. Thank you for that comment. And thank you for the compliment on behalf of the Program. With regards to explanations, if you would look at one of

the results page. For example, your mercury lab results, we had to balance describing things simply with brevity. So what -- we have attempted to do what you're referring to. So there is a bullet under What Can I Compare My Levels To? National levels, we have defined median and 95th percentile. And a lot of work was put into trying to develop language that was both easily understandable as well as brief. And this is the way that we've attempted to describe it.

So the median is described as half the adults tested in the U.S. had a level above the median and half below. That's for the NHANES. And the 95th percentile is described as 95 percent of adults tested in the U.S. had a level below this number. Again, that refers to the NHANES numbers.

PANEL MEMBER WILSON: Thank you for pointing that out. That's actually pretty clear.

(Laughter.)

PANEL MEMBER WILSON: I don't know if it would be helpful to add the micrograms per deciliter of blood or if that would be useful.

DR. DAS: You're right. That is something we didn't define, and we could certainly consider defining that in the future, for future results return packets.

PANEL MEMBER WILSON: And my other question was

on the MIEEP -- or on the Kaiser study in the Central Valley. This is our first one where we're working toward a representative sample. And I'm just curious about the sample size for those counties that was selected at 100, and so now we're going to go to 300. And do we know what the response rate needs to be for that to be representative?

DR. DAS: You're right. This is the first representative sample that we've recruited. This is representative of the Central Valley counties, the seven counties that comprise that area. And we're starting with 100 and expanding to 200, so 300 total. In terms of response rate, Kaiser has such a large population who are members that we will continue to recruit until we have 100. That's the intent.

So it's -- the response rate, I think, varies by county. But what we do is if we aren't successful in recruiting a participant on one attempt, we will continue to pick from the eligible participants who have been selected on the stratified sampling scheme that was developed originally.

And the number of participants, the 100 and the 200, were chosen based on our resource availability, and not based on the ability to represent the counties. So does that answer your question?

PANEL MEMBER WILSON: Yeah. Well, if I could follow it up. And then is the idea that we could expand from that, at some point, if there are resources I suppose, for a larger area within California?

DR. DAS: Yeah. Certainly, we would -- these are both pilots, even though we're calling one pilot and one expanded. We were successful in conducting the pilot, and so we decided to expand the number of individuals within that same region, but the idea would be to consider expanding to other areas of California or a larger area of California.

We would be interested in getting the Panel's input into what we should consider doing as we think about expanding the collection of a representative sample of Californians, whether it be expanding to another geographic region or to more participants within the same region or to focus on certain ethnic communities or languages spoken. But the idea is to use this as a model to efficiently use resources to collect a larger representative sample in more areas of California.

PANEL MEMBER WILSON: Right. Okay. Great. Thank you.

CHAIRPERSON LUDERER: Thank you. I also really want to applaud the Program for all the progress that you have made on the MIEEP, the BEST and the FOX studies,

especially also want to applaud you for the collaboration with the FDA and getting that alert out, because I think that really is important. It's a nationwide program and not a -- problem and not just a California problem. And also on the results return materials and on returning the first set of results to participants. It's very, very exciting, and a huge amount of effort involved.

I also wanted to just ask a question about the BEST with the -- actually two questions about the first 100 and the second 100 and the expanded study. So are those data then going to be combined for analysis from those -- the two different groups, the initial BEST and the expanded BEST?

DR. DAS: We're still under -- considering what we're going to do in terms of analysis, but they can be combined, because the -- they are the same population. The recruitment methods were the same. The common elements between the two are that they are all Kaiser members and the same recruitment criteria were used. The difference is that the language is -- the languages spoken basically are different.

So we haven't decided, but that certainly is something that we can consider doing. And so that definitely strengthens our ability to draw conclusions when we have a larger population size.

CHAIRPERSON LUDERER: And then do you have a sense of what the -- or do you know what the response rate was among the first 100 and how many people had to be contacted in order to get that 100 participant?

DR. DAS: It really varies by county. Certain counties had a higher response rate. And I don't have the numbers off the top of my head. I'm looking at Laura who may have some information. I don't have those, because there's seven counties, and the response rate really varied by county. That's something I can get, but I don't have that with me at this point.

We can certainly get back to you on that -- those numbers this afternoon.

CHAIRPERSON LUDERER: Are there any other -- yes, Dr. Solomon.

PANEL MEMBER SOLOMON: Just to add one more commendation to the list. I really appreciate the fact that the program expanded the BEST study to include Spanish-only speaking people. That was a recommendation from this Panel, and thank you very much for taking it and moving forward on it.

And a question on all of these timelines. The timelines end with an evaluation survey, but it's -- that begs the question of what about public release of the results and publication of the findings, which are

extremely important steps for the program. And I was wondering how things are moving forward on those aspects of the data release.

DR. DAS: Yes. Thank you for pointing that out, Dr. Solomon. We will include those steps in this timeline. That is certainly part of our plan. Everything we generate, all the data we generate as part of these projects will be publicly released, and we'll include that in the timeline. And we certainly have plans to publish the data.

We are planning to publish data from each of these projects. And efforts are underway for the FOX project, because we have returned results. And as we return the results and post them publicly, we are also planning to develop publications and submit.

So I'll make sure that at the next meeting we have those documented that we are actually considering doing those steps as part of our timeline.

PANEL MEMBER SOLOMON: And Gina Solomon again. Just to follow up on that. I think it would be important for the program, in terms of showing success, to make sure that as soon as, you know, feasible. Now, that there are results to really push to try to get them out there, because it's going to be an important demonstration to the State and to, you know, all of the funding entities that

the program is doing amazing work.

DR. DAS: Thank you.

CHAIRPERSON LUDERER: Dr. Culver.

PANEL MEMBER CULVER: Yeah, I wanted to echo everything good that has been said about this effort.

DR. DAS: Please speak into your microphone.

PANEL MEMBER CULVER: I said I want to echo everything that has been said good about what you've been doing, especially the development of materials to provide feedback to participants in the studies, and those who have provided samples.

I, in the early days of our meetings, voiced a concern that this was a very important part. And I was a little bit concerned that I didn't see that happening, but it has happened to an extent that is far greater than I really thought possible. It's really a beautiful piece of work, the package that is sent back to participants.

I have one question, or maybe it's a request for education. In the lead information, lead effect on blood pressure is mentioned as one of the things to be concerned with. And it's my understanding that there is about a one to two millimeter increase, millimeter of mercury increase in systolic pressure for each doubling of the blood lead level. And that that effect diminishes as blood lead levels increase. And I wondered is there a public health

concern about blood pressure in lead exposed populations?

DR. DAS: I believe the data is of public health concern. And our intent in describing the health effects in these materials were to let the public know about the most salient and significant findings for those chemicals. And so we did have to make some choices about what we presented.

Lead has been associated with increased blood pressure. And we've included it, because we felt it was a potential concern, both to individuals and to public health.

PANEL MEMBER CULVER: I'd like to be -- hear that explored even further sometime.

DR. DAS: Could I ask for clarification. You'd like to see the effects of lead on blood pressure explored?

PANEL MEMBER CULVER: Yes, but I'm not sure that this is really the responsibility or the province of this Panel at all. It would be an interesting academic exercise some day.

DR. DAS: Thank you.

CHAIRPERSON LUDERER: We'll have additional time for Panel discussion at the end. So unless there are some additional clarifying questions now, would you like to finish your presentation.

DR. DAS: Sure.

CHAIRPERSON LUDERER: Thank you.

DR. DAS: Yes. Thank you. There will be -- I just want to clarify that these were questions about my presentation to date, and I just have a few more things to tell you about, and that is additional program activities that we're engaging in.

In addition to conducting the projects, analyzing the chemical levels and returning results, we're doing a number of other things to grow and build the Program.

One is to distribute a survey asking about environmental health priorities to the California local health officers. Each county in California has a health officer, and they also have a director of environmental health. And we would like to get their input into their environmental health priorities in their local jurisdictions, and to involve them and to be of service to them and make sure that we're responding to their needs. And so we're going to be distributing the survey this summer.

In addition, our statute requires that we issue a data summary report every two years, and we plan to do so this July. We'll be speaking more about efforts that will help this data summary report this afternoon.

And finally, we are in the process of finalizing

our progress report to CDC describing what we've accomplished this last year, which is the third year of our five-year CDC cooperative agreement, and submitting a proposal for the following year, year four, and that's due on March 30th.

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DR. DAS: One thing that's not on this slide that I wanted to mention, hot off the press and so hot that it's not even on the slides, is that we have printed a brochure in Chinese. Now, you have -- you've seen the brochure in English and Spanish. And we printed it in Chinese. And we just got copies yesterday thanks to Amiko. And I wanted to pass out some copies to the Panel members. There are also, I think, some copies out front for those of you who wish to get them. And we'll be printing more of these for public distribution in the near future.

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DR. DAS: We have also issued a Request For Information. We described that we were going to do this at the last panel meeting. The Request For Information was issued in December 2011, and it went to researchers who have collected samples on California residents. And we are eliciting their proposals for Biomonitoring California labs to analyze selected analytes.

The criteria for selection were specified in the announcement that went out in December. And the period for submission has ended. We have received eight proposals, and we're in the process of reviewing them and hope to select some successful collaborations in the near future.

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DR. DAS: And once again, I'd like to thank the many staff who are part of this program and contribute time. And what I presented now and what you're going to hear in the next couple presentations are really a reflection of everybody's contribution.

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DR. DAS: And I would also like to acknowledge our many collaborators who are -- including the Panel members, who allow us to be successful in this program.

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DR. DAS: And, at this point, I think we can take more questions if there are any.

CHAIRPERSON LUDERER: Dr. Solomon.

PANEL MEMBER SOLOMON: Yes, a very impressive presentation. Thank you.

Can you give us an update on the funding for the program, where that stands at the moment. You mentioned the CDC grant, but I know that there are a number of

different funding sources, and I didn't see a slide on that, so it would be great to get an update.

DR. DAS: Our CDC funding so far is stable. We have received notice that for year four, which 2012-13, our funding will remain level, that is 2.6 million a year. As of right now, the Program specific funding continues to be the TSCA, the Toxic Substances Control Act, which is the fee-based fund collected by the Department of Toxic Substances Control.

As we receive updates on the funding source, we'll let the Panel members know. But the funding sources, as of right now, remain the same as they were in the past.

CHAIRPERSON LUDERER: Dr. Wilson.

PANEL MEMBER WILSON: Thank you, Chair. Do you have a sense on the firefighter project, when the compiled results would be made available.

DR. DAS: Our intent is to -- our goal is to present them this year to the public and to the Panel. What we would like to do is to be able to more fully analyze the questionnaire data in relation to the analyte data. And so we feel that would be the most helpful and educational, because we have collected questionnaire data and we have not completed the analysis. We feel that the data would be much more understandable and explainable if

we were to present both the analyte levels as well as the questionnaire data to put those results in context.

PANEL MEMBER WILSON: Great. Thank you.

CHAIRPERSON LUDERER: Before we have additional Panel discussion, we did allot 10 minutes for public comments or questions. Do we have any requests?

Okay. Great. Thank you.

Then we have some more time then for Panel discussion related to the presentation.

Maybe I can start off. I did have some questions about the FOX return results materials, and specifically whether you've heard back from any of the participants with questions about their individual results. One thing that occurred to me as I was looking through the packet, was I was wondering whether there were any questions in particular about the graphs that showed the individual's result in comparison to the median? Whether there were, you know, perhaps any concerns if their levels were above the NHANES median?

You know, you also gave the 95th percentile NHANES value in the table, but that wasn't in the graph. I was wondering if maybe there was any confusion about that or any other aspects?

DR. DAS: The participants received their results in January, and we have not actually received any calls

from participants, specifically asking about the interpretation of the results. And the firefighters most likely would call Dr. Israel, because she is -- she's the person who runs their Wellness Fitness exam, and they know her from the time she's spent with them or over the years.

She has not received any calls, and so we haven't received any inquires. That doesn't necessarily mean that they understand the results, and aren't confused. We haven't done a specific focus group with the participants at this point to understand whether they have any questions, but they have not been forthcoming and volunteered any questions to us.

CHAIRPERSON LUDERER: Any other Panel discussion?

Dr. Solomon.

PANEL MEMBER SOLOMON: I'd just like to hear a little bit more about the dust sampling aspect of the FOX study, what -- where that stands and what the plan is for releasing that information or communicating that back to the participants or, you know, how that fits into the rest of the things that you talked about?

DR. DAS: The dust sampling was environmental measurements that we decided to do separate from Biomonitoring California, because Biomonitoring California is really focused on human biological samples. The funding was obtained from sources outside any that I've

described to you here, but it is something that we felt was really important to understand the individual levels.

We were able to conduct the dust sampling, because we had the blessing of the Orange County Fire Authority. We made it clear at the time that we -- our intent was not necessarily to link the dust samples to individual levels.

However, it is something that we plan to look at. And I'm pretty sure that OCFA will want us to do that. We'll have questions about the interpretation of the dust samples. Our participants may have questions about how dust samples relate to their individual levels.

Our plan, at this point, is to present the results of the dust samples, and the aggregated results to OCFA, the oversight committee that allowed us to conduct the study.

And the dust sampling was conducted in Dr. Myrto Petreas' lab. And she and a graduate student are working on the analysis, and the presentation. And we will be describing that as the results proceed, and as the analysis goes forward.

CHAIRPERSON LUDERER: Dr. Solomon.

PANEL MEMBER SOLOMON: One more question. At a prior meeting, a firefighter from the San Francisco Fire Department came and made a plea for expanding the FOX

study to include other fire departments. Is there any plan or thought about doing that, at this point, or is it pretty much just going to be the Orange County one and that's all for now.

DR. DAS: You're referring to Tony Stefani who was a former firefighter in San Francisco Fire Department. I've had several conversations with staff at the San Francisco Fire Department. There are certain staff there who are interested in the collaboration. At this point, our limitation is our resources. It is something that the Program is interested in considering as resources become available. And we'll continue to actually have conversations with San Francisco particularly, because they have reached out to us.

In addition to Tony Stefani, we've been having some conversations with others at the fire department to explore how we can collaborate in the future. At this point, the Program does not have resources to plan a specific study with another fire department, but it is something we remain interested in considering for the future.

CHAIRPERSON LUDERER: Are there any other comments, questions from other Panel members?

Some other areas of discussion, maybe we could move on and talk a little bit about the BEST study, if we

get some feedback from the Panel about that study. I was very excited about the expansion of the study. That's really wonderful.

And I had a couple of questions related to that. One of them is, are there any plans to add -- to expand in terms of analytes for the study, in addition to expanding the number of participants? And perhaps you could just refresh our memory on what the planned analytes are for the BEST study.

DR. DAS: The analytes we're currently planning for the BEST study are the same as the ones in your -- in the presentation are the ones listed for MIEEP. So all the analytes that we have the ability to analyze are the ones that we're planning to analyze for BEST at the current time.

CHAIRPERSON LUDERER: And then in the first 100 that have been completed already, was the sample collection there, was that done at the individual's homes rather than through the Kaiser order system, is that one of the differences?

DR. DAS: Yes, that's correct. One of the -- the sample collection for the first 100 was done either at the participant's home or at a location that was arranged based on their convenience. So in some cases it was their workplace. But it was not done through an electronic

order system and collected at that Kaiser lab facilities.

CHAIRPERSON LUDERER: So then will there be a laboratory related issues, in terms of, you know, sample handling, quality control with the field kind of collected samples versus the laboratory samples, or maybe that's something that can be better addressed during the next presentation by the laboratories?

DR. DAS: That is one of the differences in the handling of the lab -- of the biological samples. The first 100 will have been collected in the field. We've developed very extensive detailed sample management protocols to ensure that the quality of the samples is maintained, even though they're collected in the field. And perhaps at a future presentation we can describe what was done in the field collection, because that is different than MIEEP and FOX. Those were collected in the clinic.

And so that is one of the differences, but I feel like because of the quality assurance and quality control measures, it will likely be a minor issue, but you're right that is a difference in the way the samples are collected.

CHAIRPERSON LUDERER: Certainly something that would be easy to evaluate once you have the analyzed levels.

DR. DAS: Yes.

CHAIRPERSON LUDERER: Dr. McKone.

PANEL MEMBER McKONE: Yeah. I wanted to follow up a little bit more on the BEST -- it's a small -- it's a pilot, right, so it's a small sample. And it is stratified. Do you have a little insight on what the stratification is in terms of urban, rural -- are you trying to capture gender probably, but other issues like urban versus rural, because there are urban areas in this study area, and economic class other factors?

DR. DAS: Yes, we did -- sorry, I didn't describe it in this presentation. We've described it in the past. There are four levels of stratification, urban, rural, gender, age, and ethnicity, four different ethnicity groups, Caucasian, non-Hispanic/Hispanic, African-American, and Asian. So the four levels of stratification.

PANEL MEMBER McKONE: I get -- well, one follow-up then. I mean, these are not going to be well populated in terms of power, so it will give you some insight, but at this point probably not a lot we can do in terms of actually distinguishing differences among those stratifications.

DR. DAS: That's correct, each -- because of the four levels of stratification, we'll only have a few

participants in each category that we finally end up with. The purpose of this pilot was really to test our ability to recruit participants and to collect samples for this kind of a representative sample. And with the additional participants in the expanded BEST, we hope to gain a greater ability to make some generalizations.

But, you're right, that it would be -- we will have less ability to generalize based -- in each individual group, based on just the initial 100.

PANEL MEMBER McKONE: And if you don't mind my following up. I'm just very interested in this.

In the pilot -- I mean, one of the concerns might be that the pilot study ends up with lots of non-detects, right? Is there a -- are you -- is that something that you're looking for and thinking about what protocol changes might be required. For example, if, for certain substance, you're getting only two or three hits out of all 100 participants, that really raises concerns about whether it's worth scaling that up to a larger population. Is that part of the protocol or the process?

DR. DAS: Well, I would invite the laboratories to answer that. But I would say that if we do find that, we'll certainly look at what factors might be responsible. We do have our ability to compare with the MIEEP and FOX. So if the non-detects in BEST look different than the

non-detects in other populations, then certainly we would explore what factors accounted for that.

On the other hand, if there are non-detects across the different populations, then it may not be a laboratory method. I mean, it may not be the sample collection method. There might be other factors. But I think that is something we'll discuss with the laboratory. If we find a large number of detects, what we can do to improve detection or what factors might be accounting for the non-detects.

Is that --

PANEL MEMBER McKONE: No, that's --

DR. DAS: You look like you had an additional question.

PANEL MEMBER McKONE: I just -- I'm bringing it up, because I think these are things that will come up in the future, and it's nice to start thinking about protocols. I mean, I guess an interesting issue would be if one, like male versus female, or one of the -- if you get non-detects completely in one group, and then 50 percent detects in the others, even if you only have five samples in each, I think that's enough to raise a bit of a flag about what -- you know, it can generate a hypothesis about future work.

And I think we should be tracking a little bit

the results, you know, on the Panel, so we can put our heads together to get some insight on to how to best proceed to kind of maximizes the information we get, because even -- I'm somewhat Bayesian so I believe bad information has some powerful insights, not bad, but low power information, can give you some powerful insights, if you know how to use it effectively.

DR. DAS: Okay. Thank you for that input.

CHAIRPERSON LUDERER: Dr. Wilson.

PANEL MEMBER WILSON: Thank you. I wonder if I could take us back one more time to the FOX study. And it's just a follow-up question on what you're contemplating for the publication of the findings. My sense is that this is going to be of great interest, you know, nationally, and that the recommendations that are -- you know, that are laid out in the packet could be expanded with a little bit more granularity around sort of the -- you know, there's a sentence in there about wearing personal protective equipment. That there could be additional information in there that would be of, you know, great utility to firefighters across the country.

And so I guess my question is if you're contemplating an initial publication that's in the sort of form of a research to practice kind of, you know, informational piece, as compared to a peer reviewed

journal, you know, with the goal of sort of getting the information out and distributing it as quickly as possible, you know, before a peer review process goes in, you know, through a journal and so forth. Is that something that you're considering?

DR. DAS: That's an excellent suggestion, Dr. Wilson. We had been planning a peer reviewed publication, but I think that you're bringing out a point that we should consider, and that is putting out something that is more practical in a research to practice type publication that can get out there quickly is certainly something we can consider.

I think the audiences for the two publications are quite different. And you're referring to a firefighter audience and other professionals who would be responsible for the health of firefighters. So that's something we will go back and consider.

PANEL MEMBER WILSON: Yeah, exactly. And I think, you know, sort of depending on how the results come out, I think it could have a, you know -- it potentially could have a fairly immediate effect on work practices, and as well as some of the technologies that firefighters are using for personal protective equipment and so forth.

You know, so these are sort of -- these have been questions that have lingered in the fire service for a

long time. And these are important findings that will contribute to that -- you know, that -- a dialogue and sort of controversy in various ways as well.

And I would be happy to help with that as well in the research to practice. You know, if it's something that the program is interested in doing, I'd be happy to help with that.

DR. DAS: Thank you. We may take you up on that.

CHAIRPERSON LUDERER: All right. We are running a little bit behind schedule here, so thank you again very much, Dr. Das for that overview about all the exciting achievements that the program has had and since our last meeting.

So the next item on the agenda is the laboratory update. And I'd like to introduce first Dr. Jianwen She, Chief of the Biochemistry Section in the Environmental Health Laboratory Branch at the California Department of Public Health.

Dr. She.

(Thereupon an overhead presentation was Presented as follows.)

DR. SHE: Thank you, Dr. Luderer. And good morning, everyone, and good morning Scientific Guidance Panel members. I'm happy to update you with the Environmental Health Laboratory's progress since our last

meeting.

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DR. SHE: First, it is my pleasure to introduce to you three of our new staff. We recently hired Alanna Viegas as our Sample Management Specialist. She replaced Josie Alvaran, who is working for our lead program right now. Alanna come to us from the biotech ward. And she is familiar with various analytical instruments.

Dr. Wei Zou was hired as a Research Scientist II, to replace Dr. Robert Ramage. He will work on a PAH method and PAH sample analysis. We hired Dr. Wei from DTSC, not Myrto's group, from a different group.

(Laughter.)

DR. SHE: And he brings expertise with many advanced instrumentation for both organic and inorganic analysis.

Dr. Ryszard Gajek has joined the CECBP as a supervisor -- supervisor of the inorganic unit, replacing Dr. Frank Barley. As you may remember, he was in our lead testing unit and was responsible for greatly improving our blood lead and blood metal analysis.

Alanna, Wei, and Ryszard may I ask you to stand up so we can welcome you.

(Applause.)

DR. SHE: Thank you.

I'd also like to take this opportunity to acknowledge Professor RuiFang Fan for her work. Professor Fan, who returned to her home country in China last month. Professor Fan developed PAH method and published three research papers while she worked with us. We greatly appreciate her contribution to this Program.

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DR. SHE: In last four months, we have continued analyzing samples from various projects, validating analytical method, and developing new methods.

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DR. SHE: At this moment, our laboratory is analyzing eight different class of chemicals. There are totally 40 compounds. I have described these chemicals in detail in my previous presentation.

We are also adding several more classes, as well as new chemicals, including these five methods: For example, arsenic speciation with LC-ICP-MS. The second one is the metal panel in urine by ICP-MS. We have a method able to analyze four out of six DAPs. So we tried to make this method able to analyze all of the six. So we are right now validating this new method. We are also expanding our OP specific metabolite method, and also pyrethroid metabolite method.

Finally, we are continue to improving our method

for analysis of dry blood spots and low volume of blood or serum. We expect by next meeting several of these methods will be moving into the production.

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DR. SHE: Here I like to talk a little bit about arsenic speciation. CDC -- the second column you can see that's our detection limits. CDC reported that detection limits between 0.4 and 1.7 micrograms per liter. And then we are reach the detection limit. Also, as you can see from the stability test, this is a six weeks. We kind of called a short-term storage stability test. The chemicals are stable. And from our recovery test, our method have good accuracy. This is recovery samples from the NIST standard reference materials. We're able to recover them near the -- close or near to hundred percent.

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DR. SHE: The methods still underdevelopment, for example perchlorate in urine, and also to increase our throughput, we like to automate the sample preparation procedures.

Our laboratory staff is now fully engaged with the current workload, but we expect to advance this method over the summer.

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DR. SHE: This slide shows our sample analysis

details. As you saw from the previous presentation by Dr. Das, we finished the MIEEP samples analysis. Most of analytes we finished, and we are -- for all of the finished analysis, that we also finished the peer review and the quality assurance review.

For example, for OP specific metabolite and the environmental phenols, we are ready to approve the data, and then send it to the Program.

For BEST sample analysis, we finished the 62 samples. And then for FOX, we finished about 40 samples of PAH and the phthalate analysis.

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DR. SHE: At our analytical lab, we are committed to build this lab as a world class laboratory. And in previous SGP meetings, we are encouraged by Panel members to publish our analytic method. During last two years, we were able to generate 13 or 14 drafts. And then half of them are already published. Here are three examples.

The first method, measurement of PBDE and the PCB in a single drop of blood is already on press and by Journal Chromatograph D. Actually, we also are encourage by Professor Tom Webster. He's in the audience. And we presented it last year, you know, one of the meetings, the BFR meetings, and get a lot of critical input and encourage.

Thank you, Professor.

And next two methods, we developed brand new method for PAH analysis. They're slightly different. The first one, we use solid phase extraction. The second one we use a CDC sample extraction method by the -- combined with a brand new analytical part.

So we think the first method used very low blood volumes will been very significant because it's harder to collect the blood samples. And also the last two methods will be very practical of the back-up method for the traditional, the high resolution method.

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DR. SHE: This is my last slide. We continue to finish MIEEP, FOX, and BEST sample analysis. Complete five method validation, develop method of perchlorate in urine, expand analyte list or OP specific metabolite and pyrethroid metabolite, automate our sample preparation procedures.

I want to thank all of the laboratory staff for their outstanding research and contribution.

Thank you.

(Applause.)

CHAIRPERSON LUDERER: Thank you, Dr. She. And I'd like to congratulate you and the other lab staff on all the progress you've made on method validation and

development, as well as all the sample measurements that have been completed, as well as on the publications. That's wonderful news. And I'd also like to welcome -- offer my welcome to the new staff members. I think all the SGP members will agree that it's wonderful that those vacant positions could be filled.

We now -- I think we were going to move on to the second presentation and then take questions for both laboratory presentations after.

MS. HOOVER: Either way.

CHAIRPERSON LUDERER: So I'd like to introduce our second presenter, Dr. Myrto Petreas, who is the chief of the Environmental Chemistry Branch at the Environmental Chemistry Laboratory at the California Department of Toxic Substances Control.

Dr. Petreas.

(Thereupon an overhead presentation was Presented as follows.)

DR. PETREAS: Thank you. And thank you for finding my presentation.

Hello, everyone. Thank you for setting up my presentation. So it's my turn to give you an update of what's the status of the DTSC laboratory.

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DR. PETREAS: And I will talk about our

resources, staffing, equipment, our capabilities on analyzing chemicals on the priority list, progress with the two major studies, FOX and MIEEP, and other activities which are not part of the program, but they are of benefit to the program. So in that sequence.

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DR. PETREAS: First of all, we're very happy that both of our two program-funded staff are back from long leaves. So both Yunzhu Wang and Miaomiao Wang are back and happy with us and productive.

In addition to two program staff, we had also good news, because from the State when we had this semi-freeze, we were finally allowed --

MS. HOOVER: Cell phone.

CHAIRPERSON LUDERER: I think the interference is coming from cell phones, so maybe if we could try turning them off, we can see if we can improve that.

DR. PETREAS: Okay. Back to staffing again. We're allowed permission to fill two of our State positions. Out of four vacancies in the Biomonitoring Section, we're able to fill two. And the people we hired are Dr. Sissy Petropoulou as a Research Scientist III. Originally, she was funded by the CDC cooperative agreement, so she had joined us about a year ago. And she has extensive experience in LC/MS. In fact, she used to

work at CDC before she came here. And now she's a State employee and continuing with LC/MS projects, and particularly the phenols.

The second person on board is Dr. Darcy Tarrant. And she also used to work in our lab for over two years, hired through a grant from the National Institute of Environmental Health Sciences. She has extensive experience in GC/MS. And she's the one who had done a lot of work with POPs, persistent organic pollutants, and their metabolites.

Now since Sissy transitioned into the State, back in November, we haven't been able yet to fill her vacancy. So this is still a vacancy, and we're trying another round of advertising to recruit and select an appropriate person. So we're improving the staffing.

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DR. PETREAS: We also have some new equipment. On the left is the Agilent Gas Chromatograph, GC/MS, that we just had. This is funding from the CDC cooperative agreement, and we're very appreciative for that.

To the right, we show two preparation equipment. And as Dr. She talked, it's very important for both labs to improve our throughput. So these -- this Zephyr 96 well workstation allows more automation and moving more samples through to the instruments.

In addition, we got -- I have no picture for that -- but we got a refrigerated centrifuge which is very helpful in cleaning up samples and making our background lower. So that's for the equipment.

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DR. PETREAS: Now, training. The new Agilent instrument, we had the first in-house training just a month ago. And then we have, as part of the package, a four-day intensive training at the Agilent facility in Georgia. And that will happen the first week of May. We're sending two staff there.

And we're taking advantage of this trip to Atlanta to piggyback and also visit New York Health Department, who had visited us in November here, and visit their lab. And also the CDC two-day training last week of April, just before the May. So we're trying to save on travel arrangements here, and try to get as many people trained as possible, both by visiting New York, because New York, in a way, has many things that CDC doesn't at this point. So we'd like to see how they do things, so our staff will go there. But, also, of course, CDC is the major trainer, and we're very hopeful that we get a lot of information from that trip.

And, of course, along with all our staff at the lab, we offer continuing education for the Program staff

and other staff through our seminars and APHL webinars on quality control and other issues of concern.

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DR. PETREAS: Now, going to our capabilities. I changed the format of this slide to more or less match the report that you probably got already or will be getting.

So categorizing the classes for which we have now methods validated are the polychlorinated biphenyls. There are 15 major congeners and 10 of the metabolites. We have seven organochlorine pesticides. Polybrominated diphenyl ethers, PBDEs, we can measure 19 congeners and eight metabolites.

Other brominated or chlorinated flame retardants. We have 13 brominated and one chlorophosphorus containing compound. We have 12 perfluorinated chemicals. Phenols, I have them as a separate group, but they're a bunch of -- it's -- they contain both -- I don't know if there's a pointer here. Oh good.

So TBBPA, tetrabromobisphenol A, 2,4-dibromophenol and 2,4,6-tribromophenol are flame retardants. And aiming at those at the same time, we can do bisphenol A, BPA, in the same method. So that was something we combined.

And in a separate analysis, we do pentachlorophenol and triclosan. So everything is in

serum for that.

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DR. PETREAS: In terms of the major studies, this the same slide I shad shown you on the previous update. And now we have completed all the MIEEP samples and returned their results to the Program for linking with the questionnaire data and so forth.

I should point out that we are ahead of schedule in doing the hydroxy BDEs of the MIEEP study. This was supposed to happen in the following year, but we took advantage of another study we're doing, and we're combining resources.

And now, so far, we have analyzed 30 of 141. So we're moving ahead with the hydroxy BDEs in the MIEEP. Everything else is completed.

With the FOX, we had completed the perfluorinated chemicals and it's part of the first round of results returned to the firefighters. And we started on the rest, which is the PCBs, pesticides, PBDEs and BFRs, and we're in the process of doing this analysis now.

And again, we are on schedule and we hope to finish the FOX within the next two months. We haven't started on the BEST. We haven't even received the samples in our lab year, but that will be our next project.

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DR. PETREAS: Now, I'm going to talk about some other activities and try to address some of the questions were raised along the way. These are activities that our department, DTSC, is interested in funding. But at the same time, the results or the procedures benefit the program.

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DR. PETREAS: So I want to start above with the California teachers study. This is a longstanding longitudinal study of cancer in teachers, or more correctly, females school employees throughout the State. This is a long prospective study, where I guess women with cancer are identified through the registry, and then other studies happened.

So on a substudy of this long big study, we're looking at on environmental exposures and that involves blood sampling. This is in collaboration with the Cancer Prevention Institute of California. Dr. Peggy Reynolds is a PI. I'm a co-PI on this substudy. And we're collaborating with UC Irvine, University of Southern California and City of Hope.

The study has been funded by the California Breast Cancer Research Program. And it's quite ambitious. It's a five-year study collecting -- aiming to collect blood samples from 1,300 cases and 1,300 controls of

teachers or female employees, school employees throughout the State.

So far, we have approximately 800 samples collected that are in the lab. The plan is to analyze the blood samples for PCBs, PBDEs, other BFRs, perfluorinated chemicals. In addition, thyroid hormones and lipids are done by a clinical laboratory.

In the lab, as we receive the samples and we catalogue them, log them into our system, we do some sample preparation where we aliquot, we divide volumes for the various analyses, and send for the lipids and thyroid hormones. And at the same time, we started doing the analysis of PFCs. So this is a long process.

It's not one of the biomonitoring program studies, but because of the large number of samples and the statewide recruitment catchment area, it will be of benefit to the Program overall once we get these results.

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DR. PETREAS: Another study that we're conducting with the University of Cincinnati is looking at transplacental transfer of PBDEs and hydroxy-PBDEs. We measures PBDEs and hydroxy-PBDEs in maternal serum and cord blood. And so far, results from 20 pairs were represented at the SETAC meeting Boston in November.

And the interesting thing here is that this is

something that -- it's the same methodology that will be used with MIEEP. So we learned with this small study, and we're applying the methodology to MIEEP. And the important thing is that we can measure things. So we know that we'll have results. And I'm showing you here some results of some of the hydroxy-BDEs

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DR. PETREAS: And this is just from the first ten. Now, we have 20, but the important thing is that they're measurable. So I'm not saying we can make any comparisons. The error bars are very big, which of course shows how the -- the variability to expect. But the important thing is our method is sensitive, and we can see them, so it will be very interesting to see how this method applies to MIEEP, which has many more participants.

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DR. PETREAS: Bisphenol A and bromophenols. This is our newest study -- our newest method. It's very sensitive. Much more sensitive than anything that has been published so far. We do this by LC/MS. Limit of detection, as I said, is much lower than what we have seen in publications. And we just recently tested this method with some samples that we have from contemporary women and some 1960s women just to see, can we see anything?

And, indeed, we found measurable levels of BPA,

the 2,4-dibromo 2,4,6-tribromophenols. Only traces of tetrabromobisphenol A.

One alert that we got from our collaborators that blood collected with butterfly in the sample collection process, may show high BPA. We don't know. At this point, we're doing a blind testing with UCSF, who sent us some samples that may have been collected. We don't know, so we're reporting to them to see how well we're doing on that, so we haven't finished that part.

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DR. PETREAS: Nevertheless, we had the poster, just three days ago, at the SOT, Society of Toxicology meeting. And this is, as I said, the poster was focusing on the validation of the method, but also have this little information here with the tested samples from the 60s and the contemporary ones.

Again, don't try to make comparisons about whether it's different or not. The important thing is it's measurable. And also, this shows you the relative magnitude of BPA versus the other bromophenols. So it's very encouraging and generated a lot of interest among people who visited the poster, and we have some more ideas where to go from here.

But I want to pause here, because when Dr. Calafat from CDC was here in November, she said very

correctly that having a method doesn't mean we have a biomarker. And I want you to reflect on that, because indeed BPA was not our -- BPA is measured in urine, and the vast majority of samples are in urine, NHANES is in urine. And, of course, for any prospective study, people should be planning on using urine.

However, the method -- BPA is a freebie on the other phenols that we measured. And we can think of many opportunities where there are no urine samples. For example, the teacher study does not have urine samples. We're not planning to do BPA in teachers, but that's an example of a large study, where there will be only blood samples.

And also, if we think of other archived specimens, which are serum or other -- the alpha-fetoprotein program. There are many opportunities to apply methods to measure BPA in serum. So with that, we're happy we have a method. And if it's needed, we can use it. But the focus of this was the BFRs, which is the 2,4-dibromo, 2,4,6-tribromo and TBBPA, and we have a method for those.

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DR. PETREAS: Now, I want to talk about dust. And I know there was a question about dust. For the last two years, we have been working and we have methods to

measure persistent organic pollutants, PAHs. And now we added new BFRs in dust.

So we have validated protocols to collect vacuum cleaner bags and analyzes -- receive them, analyze, and so forth. There are many ways to collect dust. And each method, I guess, is answering a different question. Here, in this study, first we did in house dust, and the same methodology we applied in the fire house dust, the FOX study, we're just getting the bags from the fire -- from the vacuum cleaners just to represent an overall integration of space and time for exposure.

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DR. PETREAS: So with that in mind, I should say a little bit. Todd Whitehead was a graduate student from UC Berkeley. He now has his Ph.D., and he's a post-doc in our lab. And he worked with us on the household dust methodology. We used this study to -- this method to measure dust as part of the UC Berkeley Childhood Leukemia Study.

In that study, homes of children with Leukemia and controls were sampled -- vacuum cleaner dust, I guess the bags were collected twice. Once, originally, between 2001 and 2007. And then with additional funding, and that's where we came along, in 2010, 200-something homes were revisited. So we have two samples from each house.

And interestingly, we haven't completed all the analysis, but we see -- in fact, we don't see any statistically significant decrease in the concentration of the penta-BDEs or the Deca-BDEs. We do see some decrease in the Octa-BDEs between the times of sampling.

So, at this point, we're thinking and speculating, that maybe this reflects different products and use patterns. For example, the Octa-BDEs are related to electronic devices, which is something that you more often replace. And you may be between 2001 and 2010, you had different television or cell phone or something, but your carpet and your drapes and your sofa are still there.

The take-home message is that PBDEs may persist in the dust for many years after the production has ceased. Another interesting side information is that we saw evidence of debromination of the Deca-BDE.

Originally, the thought was that Deca-BDE is like a rock. There's no problem. You don't get exposed to it. But now we see, at least with these dust samples, that a lot of the breakdown products of deca are present and they shouldn't be there.

So that's the work with the dust. And we're applying the same methodology, as I said, to the firefighters.

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DR. PETREAS: So I can tell you that I don't have data to show, but we have a validated method now for these additional BFRs. And our data so far show that they're present, both in the house dust and in the firehouse dust. So this is a new piece of information for us, because we had never measured these before. And now we have another tool to measure these compounds in dust, and adds to our environmental sampling and exposure assessment for our studies.

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DR. PETREAS: So with that, I'll stop with questions. One thing I want -- I had a note here from Dr. McKone, you had asked the question about -- I thought the concern was not only with the statistical power to tell differences between the different cells, if you stratify. But those -- in terms of resources, why are you measuring things if something is non-detect?

And, at least on that point, I should say these methods, both labs are not one method, one analyte. So maybe some of the BFRs or some of the PAHs, something, may not be present in every sample, but there won't be a waste of time, because at least something would be measurable. So maybe there will be enough statistical power for those to contrast.

So I'll stop here, if you have any questions for

both of us.

CHAIRPERSON LUDERER: Thank you very much, Dr. Petreas. And again, congratulations on all the progress being ahead of schedule and analyzing the samples for the MIEEP and the FOX, that's wonderful news, and the new methods that have been validated.

We have time set aside for some clarifying questions now for both presentations from Panel members.

Dr. McKone.

PANEL MEMBER McKONE: Yes. I actually want to -- not the question of statistical power, but the issue of dust on that slide where you -- where in your talk you make the point about there's a lot of persistence in dust. I actually think one might -- I've been working a lot with the mass balance in doors and indoor environments, commercial buildings.

And one of the things that seeing is that I don't think the dust persists that long, but the chemicals persist in the dust, and it's because a lot of these compounds have really high lipid solubility, very low vapor pressure, and they do persist in building materials. Like, I mean, there's measurements. John Little, you know, is looking at vinyl and penetration of chemicals. So if they go into things like vinyl and carpet, they stay for a long time.

So I think one other hypothesis for exploring that is that if you -- if they persist in the indoor environment for a long time, they won't be in the air. They'll be hard to find in the air, because their vapor pressure is low, but they will be easier to find in the dust. So the dust may be the sentinel as opposed to the storage medium, right? The storage is probably in building materials, but the dust is what's the sentinel medium for telling you kind of what the -- what I would call the overall fugacity of the system. So you might want to look at that hypothesis.

DR. PETREAS: You're right. These chemicals may persist on films, on window panes, on other material, on furnishings, but the dust is a convenient and consistent way of measuring them. So it's kind of having a tool to measure these.

PANEL MEMBER McKONE: Well, the only reason I raise this, is that if somebody -- you know, it's the perception. If you say, oh, well, these are persistent in dust, people will say, well, let's just remove the dust. Let's clean the house. But the problem is that the chemicals stay. I mean, you can get rid of the dust, but as new dust comes in --

DR. PETREAS: Correct. You partition it.

PANEL MEMBER McKONE: -- it just equilibrates

with the reservoir. So the reservoir is not in the dust. The reservoir is in carpet, walls, vinyl, furniture, PUF. All these things just keep replenishing.

DR. PETREAS: So we can think of dust as a passive sampler for whatever is --

PANEL MEMBER McKONE: Actually, I think skin might be a passive sampler too, but we don't want to get into that.

(Laughter.)

CHAIRPERSON LUDERER: Dr. Solomon and then Dr. Wilson.

PANEL MEMBER SOLOMON: Yes. This is a question for Dr. She. About arsenic speciation. And I'm thrilled to see that the lab is getting there with the arsenic speciation method. This is going to be, I think, very helpful. And I'm showing my ignorance, but I was hoping you could talk us through the stability column to help explain a little bit more -- put those numbers in context about what they mean. I don't know if it's possible to bring that back up.

And the other thing was the percent recovery for most of the forms of arsenic were really quite good, but the trivalent form of arsenic is actually kind of -- very important clinically. And that had the lowest percent recovery at 81 percent, so that made me a little nervous.

And I was wondering if you could talk a bit more about that, because that would be the -- as a clinician, the one that I would care most -- you know, very much about.

DR. SHE: Regarding stability, we use in-house prepare the quality control samples. We did a six week, we stored the samples in the minus 70 degrees. And then each week we take one sample out and then thaw it. Actually, each week we have almost two samples. Dr. Ryszard, if I'm wrong, please correct.

So we take out the samples and then we did basically almost 12 up to 14 samples. We did a statistic on the CV to see the variation. That's only stability we did so far. The other stability, like the post-preparation stability, and store and refreeze stability, we still needed to do it. This is only one test to show at least under the storage sample can be hold and time capped so long before we analyze it.

PANEL MEMBER SOLOMON: So just to clarify, so does that mean that over the -- at the end of the six-week period the levels of arsenobetaine were within 12 percent of where they were at the beginning of the sample period, or, I mean, with plus or minus 12 percent of the original level, is that what that's measuring?

DR. SHE: We can understanding in that way; we developed also 14 sample statistics over the period from

beginning to the end.

PANEL MEMBER SOLOMON: Okay. Thank you.

DR. SHE: And regarding recovery questions. This sample is NIST standard materials. Arsenic III with a of recovery 81 percent. Generally speaking, if you have an analytical method, if the recovery of the target analytes is between 70 to 125 percent, it is considered to be an acceptable method.

So 81 percent is one of the lowest, but still in the accepted range for these test materials. We are aware this -- for the toxicity, like, it means the most toxic form. And we hope we can improve in the future. It's acceptable, but better we get -- improve it.

CHAIRPERSON LUDERER: Dr. Wilson.

PANEL MEMBER WILSON: If I could just follow up on Gina's question on the stability. So what you're saying is that that -- those values are the standard deviation of your samples as a percentage of the mean?

DR. SHE: Yes. Yes.

PANEL MEMBER WILSON: Okay. And then do you have a -- does it reach a -- over the course of those six weeks, does -- did it reach a place where you felt it was stable or was it continuing to decline up to the end of those six weeks?

DR. SHE: And, generally, CV reflects the random

error of analytical measurement, is not a measurement of a trend. So if we saw a trend, then we might have a problem or a systematic error, procedure.

But so far, I think this is a measurement of a random error. So within the six months -- within six weeks we can show our data has fluctuated around the mid-averaging.

PANEL MEMBER WILSON: Okay. So it's instrumental variability?

DR. SHE: Yes.

PANEL MEMBER WILSON: It's not a degradation of the sample?

DR. SHE: No. We did not find a degradation.

PANEL MEMBER WILSON: Okay. Yeah. Thank you. And then I had another -- could I follow up another question with Dr. Petreas.

On the new BFRs in dust, are those -- are any of those -- or do you see those as degradation products of other known flame retardants, or are those new -- sort of new flame retardants that you're starting to see?

DR. PETREAS: These are new for us, but they have been reported for the last couple or three years. So these are new BFRs. They're not metabolized for breakdown products. So they're part of the Fire Master and part of other replacements to PBDEs.

PANEL MEMBER WILSON: Okay. Thank you.

CHAIRPERSON LUDERER: Dr. Alexeeff.

OEHHA ACTING DIRECTOR ALEXEEFF: Thank you. I have a question for Dr. Petreas. I was wondering about for the bisphenol A, you had mentioned that you had a lower detection limit for measuring bisphenol A in serum. And then you also said that bisphenol A is usually measured in urine. So I was just wondering, do we know the relationship between the levels that are measured in serum versus the levels measured in urine?

DR. PETREAS: I know of one publication that found something within 10 to 40 times higher levels in urine than in blood. So by all means, I mean, if you want to plan a study, you collect urine. But in case you don't have the urine, this gives you an opportunity to measure it.

CHAIRPERSON LUDERER: Actually, I have a quick follow-up question about BPA too. Is your BPA method total BPA, conjugated and unconjugated?

DR. PETREAS: Yes.

CHAIRPERSON LUDERER: Great. Thank you. Because only about 0.01 percent is the unconjugated, I think, in serum, correct?

DR. PETREAS: (Nods head.)

CHAIRPERSON LUDERER: Now, I'm wondering

whether -- we're a little behind schedule here, but do we have any public comments questions? We can perhaps take those.

MS. PATTON: Hi. I'm Sharyle Patton from the Commonweal Biomonitoring Resource Center. And I just wanted to say first of all, congratulations on the great work you're doing. It means a lot to all of us. And you're doing a great job. And, of course, we look forward to the public release of data, and hope to support on that. And I think that's very important.

I just wanted to say two things. One is that we collected and tested both blood and urine for BPA in 35 people, five people in each of seven States across the country about four years and be glad to share that information with you. It's kind of interesting.

And then also in our own firefighter project that we're working with on the International Association of Firefighters, we tested 31 firefighters in 15 states. And in part of our results communication, it includes a pass code protected website for each firefighter where they can access results.

So they get their results, but they can also click on other pages that discuss the factors that modify the effects of toxic chemicals, combinations of chemicals, possibility of stress, low dose effects, non-monotonic

dose response, because many firefighters are women that we tested.

But also, I just wanted to say that we have on the results page an RSS feed that working with the IFF, we can feed out to the firefighters in the study different information that they might find relevant, which would include biomonitoring studies that would be interesting to firefighters.

So we hope to work in collaboration with you at some point when the results become public, so we can feed out to these firefighters, many of whom are captains in the union in their particular firefighting situation. Feed out information about what is coming out of FOX, in terms of exposures and also we'll do other kinds of things that firefighters we find are interested in, which includes regulations about changing the way chemical fire retardants are being regulated.

And, of course, I'm referring T-117. So anyway, it's an opportunity. I hope we can work in collaboration. We can talk more about this later, but again congratulations on all this very important work.

Thank you.

CHAIRPERSON LUDERER: Thank you very much for your comment. Do we have any another public comments?

No.

So then we do have some time, more time, for Panel discussion, particularly whether any of the Panel members might have any recommendations about priorities or comments on priorities of the two labs over the coming time frame, or any other questions related to the laboratory presentations?

PANEL MEMBER SOLOMON: Just one quick question. This is Gina Solomon. Will the laboratory directors be here in the afternoon, because I think we may have questions about some of the designated chemical issues, and the things that we're going to be looking at in the afternoon? And if so, then those questions can wait. If not, maybe we should grab this opportunity to ask some of those questions.

DR. PETREAS: I would have to leave by 2:30. Sorry.

CHAIRPERSON LUDERER: And, Dr. She, will you be here?

DR. SHE: I will be here, but maybe some questions Dr. Petreas can answer better, so if you have time.

CHAIRPERSON LUDERER: Were there some specific questions related to the afternoon for Dr. Petreas that you had?

Dr. Solomon.

PANEL MEMBER SOLOMON: Yes. With regard to -- I mean, some of the chemicals that we're going to be looking at this afternoon are related to bisphenol A in various ways. One of the aromatic phosphates, the first one that we're going to be looking at, bisphenol A bis(diphenyl) phosphate and then a number of these bisphenol A substitutes are also chemically related to bisphenol A.

And so, you know, from a laboratory perspective, my question is sort of, you know, what -- from your review of these chemical structures, how difficult would it be to develop methods for those, do they fall into different categories where some could be bundled and others less so.

DR. PETREAS: Well, OEHHA staff have done a great job at identifying all these -- they shared them with us. We looked at them. We haven't used them. We haven't touched this standard -- we don't even know if there are standards for those. But from our part, what we plan to do is talk with other people who may know more, talk with companies who make manufacture standards to see what's available and who has -- who may have information, and then explore.

I mean, some things we can guess that maybe amenable to the current method. Others, may need different approaches. But we are talking to our colleagues and trying to get this information.

PANEL MEMBER SOLOMON: Thank you.

DR. SHE: And beyond what Dr. Petreas said, since the standards are not available, our approach -- we are showing that in urine. And so it's possible first to try to qualitatively to see if they are there. We have some analytical tools to see the major peak if they show up, and then definitely also like what Dr. Petreas said, and then we find the standard, then quantify that.

So we are able to bundle them with the current urine panels, BPA's panels.

CHAIRPERSON LUDERER: Actually, Dr. She, I did have another question for you before you sit down related to the PAH measurements. I know that you've developed two methods. And my question was, is there a difference in the two methods between -- in terms of things like limit of detection, the variability, the amount of sample required.

DR. SHE: Yeah. First method was SPE. And we analyzed an equal number of the PAH, but with SPE method we include one biomarker to measure the oxidation stress. And so if that's just a difference there. And also that method, since we needed to measure this biomarker for the oxidation stress, and for -- to assess any damage, that method is not so sensitive.

This was done by a visiting professor. It's kind

of with her own resource, and bring from China government. She has experience in this area, so we said okay. If you develop PAH, other things, that's kind of easy bundled together. She developed that method.

So for the second method we basically used CDC's sample cleanup procedure, which used liquid-liquid extraction. CDC's traditional method liquid-liquid extraction derivatives and then use LC -- use GC/MS. We thought maybe pull out clean-up procedure. We lost the samples. With just use extraction without derivatives. So we use LC/MS/MS.

So that's the method, even more sensitive than traditional method. So we need less sample, we can detect more. If only for PAH, the second method is better.

CHAIRPERSON LUDERER: Thank you.

Dr. Solomon.

PANEL MEMBER SOLOMON: I'd just like to follow-up on discussions we've had at prior meetings about non-targeted analysis. And I know that that's something that CDC isn't very enthusiastic about, but I remain somewhat enthusiastic with trying to explore that. Is there any progress on that front? I know there'd been interest in potentially obtaining additional equipment that would help make that possible, and investigating doing some non-targeted screening.

DR. SHE: For non-target screening, on one hand we need a different set of instruments, which actually allow to fix that. Many instrument you can do it. We have a partial instrument can do this kind of work. Like, we have LC P55 hundred the Q Trap, which allow you to do the predictive multiple reaction monitoring.

And then this kind of tools allow you to do certain identification work on the screening, because of scan speed. We also have a high resolution, which provide accurate mass through on the library search.

And that it required a different set of instrument, we also required the chemist to have a high level of knowledge. Gladly, we have the people in the house which have that -- we have deduct a low compound identification for many years, not for this Program purposely. It happened for the other things.

For example, about 20 years ago, I helped develop a system called ASES/MS, which is standard for automatic structure elucidation system, which use mass spectra information to do the compound identification.

Recently, we hired a Dr. Wei Zou. He work in University of Davis with Dr. Fiehn's lab, have a lot better ground with metabolic knowledge in there. So his knowledge also fit in, so when we -- program needed, we at least have a staff ready. We have partial instrument.

And, you know, better way if we can have more resource buy better instrument will be better. But currently, we can do very limited work on that area.

CHAIRPERSON LUDERER: Dr. Petreas, did you also want to comment on that.

DR. PETREAS: I just want to add, he's right. It's not a priority at this point. We are -- I mean, you need the right instruments. So we have good instrument, not the TOF, what we call -- which is the one that we are planning to get on our fifth year of the CDC grant. In the meantime, we're talking with people who are using such instruments, and try to get the pros and cons. And technology is getting better, sensitivity is getting better and prices are coming down, so it's good.

And we hope by a year from now, we'll have more information and we can have more decision on what needs to be done, but that's the plan. You need the right tools and the right people and the right environment to do this work. But this is really crucial, because there are so many things that we are not looking for.

CHAIRPERSON LUDERER: Dr. Solomon.

PANEL MEMBER SOLOMON: One follow-up question. This afternoon, we're going to be looking at how to sort of deal with all of these potential bisphenol A substitutes, and how to prioritize them, and which ones we

might want to, you know, move forward. And, you know, so one theoretical possibility might be to request that the lab do sort of -- you know, sort of a non-targeted screening that would try to evaluate a number of samples, since we know the molecular weights of all of these chemicals, you know, to see if they might be present on some of the samples that the lab already has.

Is that feasible, something like that? Would it be, you know, something that you actually could do and perhaps bring back to the Panel if that were something that Panel wanted to do, or is that something that really is beyond --

DR. PETREAS: I think it's a good idea, but primarily this would be in urine, correct, because we have -- first of all, we have more volume, and you have higher volume, higher concentrations, and you expect to see most of them in the urine, so I think that would be in your --

DR. SHE: Yeah. Right now, as I mentioned, for the urine, we have this LC Q Trap, which allow us to the predictive MRM and the MS/MS III, so which would allow us do the metabolite profiling. So this kind of work we can do with current to -- maybe not the best tool, but can get some information for the phenols, bisphenol S, bisphenol F. We can try to verify that, if we needed it.

PANEL MEMBER SOLOMON: Thank you.

CHAIRPERSON LUDERER: Are there any additional comments, questions from the Panel?

Okay. I think we're actually on time.

MS. DUNN: It's a little out of order, but there was a question that came up for Dr. Das. So I don't know. I think it's a pretty quick question, if that would be possible.

CHAIRPERSON LUDERER: Question from the public.

MS. DUNN: Yeah, a question from the public.

CHAIRPERSON LUDERER: This is -- sorry.

MS. BUERMEYER: Nancy Buermeyer.

CHAIRPERSON LUDERER: Thank you.

(Laughter.)

MS. BUERMEYER: Nancy Buermeyer from the Breast Cancer Fund. And I want to start by adding the Breast Cancer Fund's congratulations and appreciation for the very impressive presentations from both the labs. Although, I didn't understand a lot of that.

(Laughter.)

MS. BUERMEYER: And from Dr. Das. So my question was we are excited about the return -- the results return work that you've done. It's an incredibly impressive package, and we're looking forward to that process continuing. And as you probably know, it's been a little

bit controversial nationally. And, you know, we're very excited about the great leadership that California is showing in this area.

So my relatively simple question is, the results are offered upon request from the study participants. So I'm interested in the rate of requests, how many of the 106 firefighters asked for their results to be returned, for all of the studies not just the firefighters?

DR. DAS: Right. And so far, our findings for similar cross studies and we haven't done a thorough analysis about what percentage of participants request their results. But just our -- just on brief glance, the vast majority of participants do want their results. There maybe a few here and there who don't wish to receive their results, if any, but I would say very close to all participants would like to receive their results, regardless of which study we're talking about.

So we're really talking about the three studies that Biomonitoring California has initiated, BEST, MIEEP, and FOX.

MS. BUERMEYER: Thank you.

CHAIRPERSON LUDERER: Thank you very much. So we will break for lunch now, and reconvene at 1 p.m.

But before we break, Carol Monahan-Cummings, who is the staff counsel for OEHHA, is going to give us a

reminder about Bagley-Keene.

CHIEF COUNSEL MONAHAN-CUMMINGS: Carol Monahan-Cummings, Chief Counsel for OEHHA. And this is just a brief reminder that during your lunch break, if you can avoid talking about the decisions or recommendations you might be making this afternoon, and just keep your discussions in the public view at the meeting, I'd appreciate it.

Thank you.

CHAIRPERSON LUDERER: All right. Thank you.

Dr. Zeise, do you have a comment?

DR. ZEISE: No.

CHAIRPERSON LUDERER: All right. We will reconvene at 1 Thank you everyone

(Off record: 12:07 p.m.)

(Thereupon a lunch break was taken.)

AFTERNOON SESSION

(On record: 1:13 p.m.)

CHAIRPERSON LUDERER: Okay. I'd like to welcome everyone back from lunch. We're going to get started and folks will continue to straggle in, but we have a very packed agenda for the afternoon. So I'd like to call the meeting back to order.

And I would like to, once again, reintroduce Dr. Rupali Das, the lead of the California Environmental Contaminant Biomonitoring Program, who is going to provide a progress report on initial results from Biomonitoring California collaborations. And this agenda item is also going to include Panel feedback on the initial results and input on specific questions regarding the Program's upcoming data summary report that's projected to be release in July 2012.

Dr. Das.

(Thereupon an overhead presentation was presented as follows.)

DR. DAS: Thank you, Dr. Luderer. Welcome back to this afternoon's session. As Dr. Luderer explained, the agenda item that I'm going to be discussing right now is a description of the initial results from Biomonitoring California collaborations. And the document that I'm going to be discussing was posted on the website, and is

available -- and is in your packets for the Panel members, and is titled Initial Results from Biomonitoring California Collaborations.

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DR. DAS: Over the past five years or so, the Program has been building capacity and capability. And we're now just starting to present the preliminary work that we've done. The purpose of this agenda item is two-fold. First, to present to the Panel and to the public initial data from our collaborative efforts.

These results are preliminary. Our data analysis is ongoing, and we plan to present even more detailed information as we complete our analyses.

Secondly, we would like the Panel's input on the content and the presentation of these materials as a document that will be posted on the Program's website, and, in addition, will form the basis of what will be the data report that is required of the Program to be posted every two years, and we plan to post a data report this July. So we would appreciate your input as to the materials to include as part of the data report.

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DR. DAS: The document that I'm going to be discussing consists of the following elements:

And I'll highlight the contents. I won't be

going over each item in detail, but I'll describe what is contained. The contents include the key messages, the chemicals that Biomonitoring California labs can measure, a description of the collaborations, initial combined results, and what we look forward to doing in the near future.

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DR. DAS: I'd like to turn now to the three key messages that the Program would like to put forward and that are illustrated by the data that we present as part of this report.

First, the Program has measured many chemicals in California residents. Among the chemicals detected by the Program are those in consumer products, for example phthalates and heavy metals, and persistent chemicals, some of which have been banned. For example, some flame retardants that are a widely -- were widely used in furniture and electronics like the penta- and octa-polybrominated diphenyl ether, or PBDEs, and some pesticides that have also been banned, such as DDT.

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DR. DAS: The second major message of these materials is that since 2007, the Biomonitoring California labs have made significant advances in their ability to measure chemicals in people. The Program's labs can now

measure or analyze approximately 100 different chemicals in blood or urine and are developing materials and methods to test for even more chemicals of particular importance to California. Biomonitoring California has tested more than 700 Californians so far.

And our third major message is that the Program has been able to advance its lab capability and other parts of the Program, and study diverse populations by leveraging limited State resources.

The Program's collaborations include more than 10 populations across California. Critical to our accomplishments has been our five-year CDC cooperative agreement, not only the funds, but also the collaborations with the staff at CDC has been essential for us to develop our capabilities here in California.

In addition to CDC, our collaborations with our other partners in California has been essential. And these include universities, other groups, and, of course, Kaiser Permanente.

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DR. DAS: I'd now like to move to talking about the chemicals that the labs can measure. In your document that you have, I'll be referring to Figure 1 and Table 1. This is the first section of the report that shows the chemicals that the Program can measure. And the

information included in the figure and the table, show the rapidly developing and extensive analytic capabilities that allow us to detect low levels of chemicals in people.

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DR. DAS: This is Figure 1 in your document. This figure shows that the number of chemicals our labs can measure has increased more than five-fold over the past four years. The number of chemical classes is increasing, as are the number of chemicals in each class.

New capabilities added since 2007 include phthalates, perfluorinated chemicals and some pesticides, environmental phenols, and brominated and chlorinated flame retardants. We think this is a -- this bar chart really illustrates the dramatic abilities that the labs have developed over the past few years.

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DR. DAS: This is an excerpt of Table 1, which describes the approximately 100 chemicals that the labs can measure in blood or urine. This table illustrates the chemical classes or chemical subsets of the chemical classes that the labs can measure. The table includes a brief description of the uses of the chemical in Column 2, the second column here, and an explanation of the type of analyses that the labs can carry out, whether in urine or serum or both here in Column 3.

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DR. DAS: The next section of this report describes the collaborations that Biomonitoring California has entered into. I've already mentioned that we have collaborated on studies of more than 10 different populations. The populations included in our collaborative studies include, as you already know, pregnant women, infants, firefighters, residents of agricultural communities, and pre-adolescent girls.

The CDC cooperative agreement has more than doubled the resources available for building our biomonitoring capacity.

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DR. DAS: The description of the collaborations are presented in two ways; in narrative format and in table format. We have divided our collaborations into two categories. The first category are the full project collaborations. And these are the ones that you've heard the most about over the last few years. These are the projects that Biomonitoring California has been involved with from the start, and has been involved in the design, in the recruitment of participants, in collection of samples, and the analyses, as well as returning results.

The projects that we are categorizing as laboratory collaborations are those where the samples may

have been collected by other researchers, who are outside of Biomonitoring California, and our labs are analyzing the samples.

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DR. DAS: The next couple of slides show an illustration of these two sections. First, the narrative description. This is an example of a narrative description of a full project collaboration that you've heard a lot about, the Firefighter Occupational Exposures Project, or FOX.

I'm not going to go through this in detail. This is just to illustrate what that table contains. This is the kind of description that's presented for a full project collaboration in the narrative explanation.

This is an example of a narrative explanation for a laboratory collaboration. And the example we've used here is the CHAMACOS study.

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DR. DAS: Following the narrative descriptions of our collaborations, there's a table. And again I've used FOX and CHAMACOS as illustrations of how a full project collaboration and a laboratory collaboration are presented in the table.

The table lists the collaboration, the number of participants, the population, in this case firefighters

and five-year old children at the time of recruitment, the catchment area, the chemicals that were biomonitored in each study, and the dates that the samples were collected.

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DR. DAS: The next section of the initial results document is illustrated by Table 3, which combines results from eight individual studies and shows the chemicals that Biomonitoring California has found so far in California residents who have been tested.

Additional analyses are underway on samples. And some of these are still in progress. And again, I want to remind you that these are preliminary results, and we will present more detailed analyses on each of the projects as these are completed.

The table displays the percentage of people in whom the chemicals were found, or detection frequency. And let me just go on to the table and describe that.

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DR. DAS: So this is an illustration -- excerpt of Table 3, which presents the combined results from Biomonitoring California collaborations.

Here listed are the chemicals that were measured. And for illustration purposes, this slide shows metals and PFCs. The study in which those chemicals were measured. And the study is listed as a letter, which is not defined

here on the slide, but in your document it's on page 15. Each of the -- or the page that the table is on. Each of the studies for which the chemicals were analyzed is listed as a letter for ease of presenting in the table, the number of people in which that chemical was analyzed and the detection frequency.

The detection frequency, I'm sure the Panel members are familiar, but for members of the public who are not familiar, does not indicate the level of a chemical that is measured, nor does it provide information on possible health effects. The detection frequencies listed here also are not necessarily representative chemicals that can be generalized to the State's population as a whole, because these were smaller studies that are combined here for this results presentation.

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DR. DAS: Finally, we look forward to doing even more and presenting more detailed information to the Panel. Detailed findings on individual studies will be released in the near future as the project collaborations proceed.

Our laboratory capability and capacity are continuing to expand. And the Program has launched a pilot study in the Central Valley with the help of Kaiser, with participants selected to approximately represent the

adult population of that area. The pilot project will help us to build capacity and to produce data representative of the region's and the State's general population.

Finally, Biomonitoring California findings will be critical for informing State programs to protect the public from harmful chemicals and making those efforts more targeted and cost effective.

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DR. DAS: At this point, we would like to get any questions or comments from the Panel addressing what I've covered so far.

CHAIRPERSON LUDERER: Thank you, Dr. Das, for that presentation and for all the work that has clearly already gone into this preliminary document in preparation for the report.

So we have two -- some time now for Panel questions, clarifying questions, and general comments. Then we'll take public comment. And then we have a longer period of time for Panel discussion. So do you any of the Panel members have clarifying questions?

Dr. McKone.

PANEL MEMBER McKONE: Probably a question as much as a comment. But it's really impressive that we have so many chemicals that are going in. And yet, on the other

hand, I go well there's a hundred, maybe could do 200, but how many thousand are out there? And I just raise this, because it's a question I often get about, well you're finding these chemicals, but what about the ones you're not looking for, don't know how to look for, what do we know about those, and what can we generalize?

I just -- I kind of raise that as something I think we have to be aware of, is that we're -- you know, I don't know if we're seeing the tip of the iceberg or we're seeing the center of -- you know, if we're really -- the question I always ask is did we pick the right ones, in terms of health outcomes or levels of concern or some other reason. And I think it's just going to be an ongoing issue, but it is -- it sounds like a lot, but I'd like to see a plot of, you know, some day of how many that is compared to the 5,000 that are in wide use and common.

DR. DAS: Thank you for that comment.

CHAIRPERSON LUDERER: Dr. Wilson.

PANEL MEMBER WILSON: Thank you. It's similar -- I have a similar thought and then a question. That one of the ways we framed the -- you know, the data from CDC that sort of has the same limitations as Tom is describing is saying that Biomonitoring California looked for and found, which is a little bit different than saying found, and is sort of just a slight language change, but it sort of gets

to Tom's point, that, you know, we're looking for these and we found all the ones we were looking for.

But it might help underscore that to say that something to the effect that there are -- you know, that doesn't necessarily represent the complete universe, or something to that effect.

I think that's -- it is useful. I also -- I think it's helpful the way you've framed these first three initial findings that are on the second page in the boxes. And simply -- it's just sort of a statement of facts, without, you know, trying to put interpretive information in there up front. I think that's -- I think that's smart. I think it's a good approach just to sort of put that up. And I understand this is going to be a public document that goes up on the website. That's this language.

DR. DAS: Well, the document is public, because it has been posted to the Program's website.

PANEL MEMBER WILSON: Right.

DR. DAS: And we are looking for the Program's -- I'm sorry, the Panel's input into the data report that will also be a public document posted on the website. This is a preliminary document. We're looking for the Panel's input as to how it should be finalized, because the final document will become a public document as well.

PANEL MEMBER WILSON: Right. I think the -- you know, the way you've framed it is really nicely done.

And then could I just ask a question about the -- on the collaborations, did the Firefighters Association in Orange County play a role that would be considered a collaborator?

DR. DAS: Yes. We consider them a collaborator, because they were instrumental in allowing us to do the FOX study. We've presented findings on an ongoing basis, not the data, but just our progress reports. And the individual firefighters or the labor representative has played a role in recruiting firefighters or arranging for focus groups and allowing the study to proceed. So, in that sense, they are collaborators.

PANEL MEMBER WILSON: Yeah. I mean, I think it would be helpful to make that explicit in the section that's under full project collaborations, that the collaborators were, you know, both the Orange County Fire Authority and, it's probably, International Association of Firefighters Local something for Orange County. That would -- I think that would be helpful and it would be -- just send a nice message.

DR. DAS: Okay. Thank you for that input. We will take those into consideration as we proceed in finalizing the document.

PANEL MEMBER WILSON: Thank you.

CHAIRPERSON LUDERER: Dr. Kavanaugh-Lynch.

PANEL MEMBER KAVANAUGH-LYNCH: Hi. Mel Kavanaugh-Lynch. I really enjoyed this report very much. And it was great to see the progress that the Program has made to date all gathered together so nicely.

I think part of the comments that have already been made are addressing kind of putting that work into a context. And I agree that I kind of missed that contextual aspect of the report.

I also kind of missed a "So what?" at end, sort of the implications. So being fully aware that the findings -- that these are pilot studies, and that the findings are preliminary and all of those qualifications. I think a -- so, at the end, what does that matter to the people of California?, would, be a good thing to add.

So, you know, is it a wonderful thing that the State now has the capacity to biomonitor these, and why is that a great thing? Is it interesting or intriguing at all that certain findings have been discussed thus far, and what might the implications of those findings and other related findings that might come up in the future be for the residents of California? I think I would imagine most of the public who might read this report would be most interested in that kind of intro section and that

conclusions section, and a little bit less in all the details in between.

DR. DAS: Okay. Thank you for that input, and we'll consider adding those as well.

CHAIRPERSON LUDERER: That actually -- I had sort of a clarifying question I think relates to what Dr. Kavanaugh-Lynch was just saying, which is what do you see -- who is the primary audience for the report going to be? Is it intended to be, you know, everyone, the public, legislators, the, you know, scientists, or is there a particular target audience that it's mostly intended for? I think that kind of affects what sorts of things and how the things would be presented in a report.

DR. DAS: Yes. That's a very good question, Dr. Luderer. I think we feel that our primary audience is the public and the legislators and a secondary audience are scientists and people with more technical background, because scientists will -- the information that they're interested in will come out in other formats, like published papers and so on.

CHAIRPERSON LUDERER: Dr. Solomon.

PANEL MEMBER SOLOMON: I agree with what others on the Panel have said, that this is a very nicely done report, really clear, good format. The only minor point is that the -- you know, like looking at the PBDEs, it

lists them by number. And then if you're, you know, kind of a member of the public, it begs the question of, well, are any of these translatable to anything you might have heard of? You know, legislators, for example, have heard of things like deca- or penta- and wouldn't necessarily know how those map against the ones listed here.

So it might be helpful to have a little brief explanation when -- you know, when there is something that can map to a different term that people might have encountered, because in the previous table it just sort of defines PBDEs generally as a group or PFCs generally as a group. And some of these also have specific other names or uses that people have heard of.

DR. DAS: Thank you, Dr. Solomon. I just want to ask a question. Are you referring to then inserting a commonly used name with the -- you're talking about Table 3?

PANEL MEMBER SOLOMON: Yeah, in Table 3. So you could even put in the first column a parenthetical after certain numbers there, and say, you know, BDE 209 parentheses deca-, something like that.

DR. DAS: Okay. Thank you. That's certainly a good idea, and we'll do that.

CHAIRPERSON LUDERER: Okay. Do we have some public comments? I'd like to take some time to either ask

these people to come forward or if they were by email to read them.

MS. DUNN: Can I just say, we moved the mic over here for the commenters. Sorry, it's a little bit more of a walk, but it's better for the video camera.

CHAIRPERSON LUDERER: All right. We have a comment from Diana Graham.

MS. GRAHAM: I just wanted to congratulate the Program on the breadth that it's gotten to now. And I'm an analytical chemist, and I really maybe should have made this comment this morning when we were talking about the data.

But I would like to see, as Dr. Solomon commented, the data released as soon as possible, so that people can see it. I think, you know, it's very interesting to the people in California as to what you're finding, how it relates to the NHANES data that's already available. And I think that -- when you did the firefighters return information, I thought that was a great part of it, so that the people who are getting the information can say, well, here's what I have or here's what the State of California people have, and here's what the rest of the country has, because I think that gives them sort of a bases, even if we don't have levels of concern. We can look at that and see where we are.

And there has been data that was released like a couple years ago, for example, the farm workers study. We had a handout at one of the meetings, but it doesn't appear to be on the website. And I don't know why we can't have data that's already been released up on the website so people can see it. If I could just put that out as a comment.

Anyway. Thank you.

CHAIRPERSON LUDERER: Thank you.

Dr. Das, did you want to answer that question?

DR. DAS: If we're referring to some of the collaborations for which results were returned to participants, if information is already publicly available in another format, it's already there. What we chose to do here was to present everything in a uniform format. So certainly if something is publicly available, we will consider linking that information to this report.

And as information becomes publicly available, we'll continue to link it to this report. Certain studies have had information presented to participants and certain haven't. But for purposes of consistency, we chose to use a single report. But we can certainly change that going forward for individual studies as the information is available.

CHAIRPERSON LUDERER: Dr. Solomon.

PANEL MEMBER SOLOMON: In Table 3, just going back to that, you know, you list the detection frequency, but nothing about the, you know, median or range. And is that because you don't have all those data yet or because you feel -- don't feel comfortable putting that information out yet?

You know, it would be helpful, as soon as possible. And I guess that sort of leads to the question about public release of information, whether the Program envisions doing that, you know, waiting until the participants have been informed and then have had an opportunity to ask questions, or sort of doing the two processes in parallel, so that the information is released to the participants, you know, around the same time as the aggregated data are made available to the public.

I would tend to, you know, encourage trying to do those two as close to at the same time as possible, instead of waiting, just because of the importance of making the data publicly available.

And also, you know, if you're trying to publish the data, there's a lag time there anyway, so you may as well sort of try to move that process forward quickly.

Anyway, that's a bunch of different questions all rolled into one.

DR. DAS: In answer to your question about our

decision to post the detection frequency and not other statistics such as median and percentiles, the data certainly could be obtained. There are a couple of different considerations, and we are looking for the Panel's input. These are a combination of a number of different studies. One of the issues we'd like your feedback on is the advisability of producing statistics, such as median and more range and percentiles on combined studies where they've been collected under different circumstances, not a single population. So we'd like your feedback on whether that's scientifically advisable.

And, in terms of your question about the sequence of returning results to individuals and posting, our intent for the studies with -- our full collaborations where we've been responsible for designing the study and are responsible for returning the information to participants, our desire is to return the results to participants before public disclosure of the results. And so we certainly intend to disclose the results soon after returning the results to individuals.

For this preliminary results return, we've chosen to present -- have a uniform presentation for all studies. And these were the common elements, but we do -- would like your input regarding the additional information to present on the studies, whether it's scientifically

advisable.

And we do have -- I just wanted to say that we do have a set of questions that follow. And I think some of your questions now are getting into the questions we have for you. So Dr. Luderer, I don't know if you want to go to that now.

CHAIRPERSON LUDERER: I was going to suggest that. Yeah.

DR. DAS: So part of the reason for mentioning this on the first slide is to ask the Panel a set of questions that would guide us going forward in how this document should look like. This, again, was just to get you thinking about it, and to give us advice.

Before I go into the questions that we have for the Panel, I wanted to let you know, as I'm sure you're aware, that this document, as simple and as barren as it may seem, it involved a lot of work on the part of many staff, both staff -- staff in all departments, Sara Hoover in OEHHA, and Amiko Mayeno in the California Department of Public Health were, I'd say, the two main leads who put in a lot of work, but other staff as well. So I wanted to acknowledge their considerable efforts in putting this report together.

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DR. DAS: And now I want to go on to the

questions that we have for the Panel. There are several questions. I'm going to go through all the questions and then we can go back to the ones you'd like to address.

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DR. DAS: The first question is with regard to the three main messages contained in the materials for the Panel, are these messages useful and appropriate? And are there other messages that should be included?

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DR. DAS: Secondly, with regard to Table 1 and Figure 1, the chemicals that Biomonitoring California labs can measure, are these groupings of chemicals useful and understandable?

Secondly, should additional information suitable for a technical audience be included, for example, information on the method detection limit?

Third, is there other chemical-specific information that would be helpful to include?

And finally, are there any suggested changes specifically to Figure 1?

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DR. DAS: A third question for the Panel is with regard to the Biomonitoring California Project collaborations that are described in the narrative, as well as in Table 2, is this level of detail adequate for

the data summary report, which we are required to submit by July of 2012? And is there any other information that should be included?

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DR. DAS: Next, referring to Table 3, Initial Combined Results from Biomonitoring California Project Collaboration, is the information in the table useful and clear?

Is the detection frequency useful to report for the initial combined results?

And would any other information be useful to include in Table 3?

And -- okay, so that was it.

Those were the questions we would like the Panel to address, and we can do so in whatever order you would like to.

CHAIRPERSON LUDERER: Since we're already -- we're kind of starting a discussion about that last set of questions, perhaps we can start with that one.

Dr. Solomon, did you want to add something to your earlier comment?

PANEL MEMBER SOLOMON: I recognize what you're saying about lumping together somewhat disparate study populations, and the question about whether that's appropriate. I think that -- I mean, the bottom line here

is that all of these studies are being done through the same lab, using the same method of subpopulations in California under the aegis of the Biomonitoring Program.

And so I would pretty strongly lean toward presenting aggregate numbers program wide for certain purposes. I don't think you're really going to want to publish that in a peer-reviewed journal. I think you would publish each of these subpopulations separately. But for the report back to the Legislature and to the people of California, I would encourage, you know, sort of putting the aggregate data for California -- you know, all 700 Californians so far together, and then as -- you know, as numbers become available for the substudies, then also presenting those separately.

And -- well, okay, and then I'll hold off on my input on some of the other questions.

CHAIRPERSON LUDERER: Dr. McKone.

PANEL MEMBER McKONE: Yes. I think I would concur pretty much with Dr. Solomon, probably expand on that a bit. I think when you have data from different studies, there's some things to avoid. I mean, you can pool the information. And I think that's appropriate, and then even maybe make available all of the information.

I'd be careful though about means and medians, because the relevance of a mean and a median or standard

deviation is when you're pooling different data sets from different sources, can get you in trouble in terms of protocol and interpretation.

And again, not seeing the information, I'm not sure how to report it, but probably the range of some rank order of high to low, and how many were in certain ranges would still be very useful, and yet not violate this -- I mean there's kind of -- you're kind of violating the rules of statistics to pool two dissimilar data sets, and then call them a single data set. That can get us into a bit of trouble.

But I don't think displaying ranges of pooled sets is violating any sort of rules of statistical presentation or communication. So I would be in favor of seeing more information. It's certainly, in our minds, like, okay, so you got so many hundred percent detects, but what were they? What was the rank, the range, some of the -- just the magnitude -- some rough idea of magnitude.

DR. DAS: Laura Fenster from our Program would like to respond to your suggestion.

DR. FENSTER: I just have a question for clarification in terms of --

MS. HOOVER: Get closer to the mic.

DR. FENSTER: Oh, closer. Okay.

I have a question for clarification, which is I

have been very concerned about combining results from cord blood in pregnant women in this aggregate data. And so I and other scientists, I think, would really appreciate, given you're recommending combining data across different groups, what you think about those populations?

CHAIRPERSON LUDERER: Dr. Wilson.

PANEL MEMBER WILSON: Sure. I mean, I think it's -- Tom, I think, is starting to describe this. And I think if I understand it correctly, what you're saying, Tom, is that you have -- each of these would have a different distribution and standard deviation and so forth. And if you dumped them into a single data set, you violate that basic -- that principle. I guess -- and one of my concerns about combining them is that we do lose the potential for identifying and illustrating highly exposed subgroups, if you will.

If there are -- if some of the data from the -- any of the individual populations is, you know, a lot higher or, you know, very different from the other ones, that seems like it would be important to be able to illustrate that.

And yet, I also -- you know, I guess this is interesting to hear from the Panel about what, you know, the scientific merit of, you know, pooling the samples. And because it's -- if we did do that, I think it would be

interesting where there's -- where there are chemicals that have also been evaluated by NHANES to place the California findings in the context of NHANES, in part because that was, you know, part of our decision-making process to identify substances that are of unique interest to California, for example. So two or three different ideas there, concerns.

CHAIRPERSON LUDERER: Dr. McKone.

PANEL MEMBER McKONE: So I'm very uncomfortable mixing media, right? I mean, I think it's confusing if you take cord blood and compare it to serum blood from -- and so I would be really uncomfortable with that.

I also -- you know, in terms of -- I don't think it dilutes the ability to pull out the population if it's there, right, if the information is there. You know, I'm thinking by analogy of other things. I know when we were doing bioconcentration studies with fish and worms and all kinds of -- we used to just do plots of everything we had. Just put it up, and then color, you know, these are worms, and these are fish, and these are polar bears. I mean, put everything out.

And, of course, you shouldn't -- you know, there's no statistical way to say, oh, the mean bioconcentration factor. But visually it's very powerful to see if they're just all over the place. Then you go,

well, there's no real theory for what's going on. If they cluster, you might develop some hypotheses. You know, I don't know how much the State wants to get into, you know, visual display of information, but I do think there's a lot of value to have it. Have more than just say -- I mean, as soon as I see somebody said a hundred percent above the limit of detection. I still -- my mind immediately says, well, what number? What were the numbers in that set? I mean, they were all above the limit of detection. But is that like 10 times the limit? I mean, where were they? I'd like to see some -- I'd like some knowledge of where the quantity is. Maybe just my brain is too quantitative.

CHAIRPERSON LUDERER: Dr. Solomon.

PANEL MEMBER SOLOMON: I agree with Dr. Fenster that mixing cord blood in, it is probably going a little too far. I don't -- it actually doesn't really give me heartburn to put, you know, people from the Central Valley and firefighters and pregnant women from San Francisco all into one sort of uber data set for purposes of, sort of, summarizing results, but putting cord blood in just because of the physiology, it's different.

And I think that that should not be -- you know, it's not an either/or about breaking out the data. I think that as soon as the data from the substudies can be

made available, that's even more important. But if we're at a point right now of trying to kind of give the Legislature and the public sort of a very general sense of what the Program has done, I think that would -- you know it's acceptable to do this.

Should I move on to any of the other questions or should I -- are we still going to stick with this?

CHAIRPERSON LUDERER: Does anyone else -- maybe we'll just see if any of the other Panel members have additional comment or input on this set of questions?

Dr. Culver.

PANEL MEMBER CULVER: I feel there's an underlying theme to all of the comments. And that is a concern for what our initial objectives were for this Program.

MS. HOOVER: Can you get a little closer?

PANEL MEMBER CULVER: I'm sorry. Shall I go back or did you hear enough?

PANEL MEMBER CULVER: I said I feel there's a common theme to much of the comments that have been voiced so far, that underlying them is this concern for how relevant what we're doing is to the original objectives of the Program as set forth by the Legislature.

And I just wonder if there isn't some way that we can sort of chart our course, as we work toward that

ultimate goal, and to show the incremental steps as they occur, because indeed the picking up of populations here and there and developing analytical capabilities in certain groups of chemicals, all fit in to what the ultimate assembly of information is that will ultimately become the Biomonitoring Program of California.

CHAIRPERSON LUDERER: Thank you. Just also to maybe try to summarize a little bit what the Panel comments have been. I think several of the Panel members expressed opinions that they would like to maybe see more information about what the chemical concentrations were, more than just detection frequency, but then I think there also seems to be a broad agreement among the Panel members that combining the cord blood with adult or serum is not appropriate in terms of, you know, summary measures and that perhaps summary measures -- I think there was a little diversity of opinion as to, even excluding the cord blood, whether summary measures like median and mean are appropriate for data -- these disparate data sets -- somewhat disparate data sets that are being analyzed here.

One additional thought that I had, and it would be interesting to hear what other Panel members thought, was whether it might be possible to -- and this goes along with what several other people said about the NHANES data, to provide the percentage of -- kind of analogous to

detection frequency, the percentage that were above the 95th percentile of NHANES perhaps or, you know, above the 50th percentile.

So not actually giving median or mean, but that gives more of a sense of, you know, were there high values, I think, which might get a little bit at what Dr. McKone was talking about.

And then I think another thing that might be helpful, even though there are only two chemicals, lead and mercury, for which you have levels of concern, perhaps to talk about those values that were above the level of concern, which I think that venue can highlight the -- you know, one of these success stories of the Program already of discovering the elevated mercury and the tracing that back to the source and then the health alerts.

And I think that, you know, maybe is the type of thing that Dr. Kavanaugh-Lynch was saying that would be, you know, showing why this is important and what some of the benefits of the program are.

So I don't know if other Panel members had additional comments related to that question.

Dr. Kavanaugh-Lynch.

PANEL MEMBER KAVANAUGH-LYNCH: I will chime in here that I'm like -- I'm on board with what most of the rest of you have said, and agree that maybe ranges are

okay, but medians are kind of meaningless when it's not a representative sample.

An alternative to providing all of the data, which, of course, all of us are itching to see, but is problematic in a number of ways, is what I was thinking of in terms of implications, is to pick out anything that was interesting. So I think the mercury and the lead are two of those. Anything else that you have seen that you were like, "Wow, that's -- Boy, that's high for -- compared to NHANES", and using those as tidbits.

Like, you know, all this data is preliminary, but thus far we have, you know, seen -- the data has been interesting in the following ways in providing little tidbits. And I also could see very much when I was reading this seeing -- you know, pull quotes from -- you know, a quote from a firefighter having received their results, like what they said about -- what it meant to them to see their results, a quote from one of the mothers, you know, that provides some, again, context and, "So what?" to the whole thing.

DR. DAS: I'll just respond. Certainly, we could -- we'll consider including the additional information in the -- what I'm hearing is the range seems to be what the Panel members have agreed to for the -- for our combined results, certainly we can present the range.

The range is not available for NHANES. The 95th percentile or percentiles are available for NHANES, and the level of detection, that kind of information, is available.

So if we were to present a range, we wouldn't have a comparable range for NHANES. We would have percentiles, but we can certainly present something that's comparable in NHANES.

In terms of the other information -- and certainly your points about highlighting chemicals for which there are levels of concern, like lead, mercury, and cadmium has an occupation standard as well, we can consider pulling out some message from the data from those.

In terms of quotes from participants, I think we'll have to discuss as a Program if that is something -- that's currently not something we're gathering, so that's something we would have to discuss, whether that's possible to include.

CHAIRPERSON LUDERER: Dr. Fenster.

DR. FENSTER: Hi. Rupa, also I heard above the 95th percentile. And I don't know if that's something that the Panel came to agreement on, that versus the range, or that in addition to the range. We'd like just some clarification, I think.

CHAIRPERSON LUDERER: Dr. Solomon.

PANEL MEMBER SOLOMON: Yeah. I actually like Dr. Luderer's suggestion to, for example, present what percent of the Californians monitored so far fall over the 50th percentile say in NHANES. And so if, you know, 20 percent of the Californians sampled so far are over the 50th percentile in NHANES, that would suggest that perhaps, you know, at least one hypothesis would be that Californians might be less exposed than the U.S. population.

And if 80 percent of Californians are over the 50th percentile for NHANES of the small -- of the sample so far, that might encourage people to, you know, get interested in looking at that. So I think that actually does raise -- is a nice way of possibly presenting that.

And I very much liked also the suggestions from Dr. Kavanaugh-Lynch about additional material to include.

CHAIRPERSON LUDERER: Dr. McKone.

PANEL MEMBER McKONE: Yeah. I want to concur with Dr. Solomon. I think, if you pick a bench -- you know, you have to be careful not to refer to means and medians and you don't have a 95th percentile, because it's not that kind of sample. But picking a benchmark from NHANES, and then ranking on either side of that is very useful. And it's -- you know, it's informative, and it's not going outside of the bounds of what you can do with

this kind of data, so it's probably a good idea.

CHAIRPERSON LUDERER: Dr. Wilson.

PANEL MEMBER WILSON: So if I understand it, is the idea that the report would say this is the percentage of the results that fall above the NHANES median.

PANEL MEMBER SOLOMON: Yeah.

PANEL MEMBER WILSON: And it's a percentage of findings, or of samples, that fell above that. Is that the idea?

PANEL MEMBER SOLOMON: As I understand it.

PANEL MEMBER McKONE: Right, or I would say just pick a benchmark. It doesn't have to be the median. I mean, that's a nice one to pick, but it's the idea of when you have data that is somewhat scattered, comes from different populations, was not intended to be -- I mean, if there's problems with it, you want to be very careful not to compare it to NHANES in any systematic way that would suggest the data you had was collected in a comparable way, but picking a benchmark, right? I mean, something that is -- I mean, by a benchmark, I mean, something that has some meaning, right, and then putting our information around it, like above/below.

We're not actually trying to do a statistical analysis. We're just saying here's a benchmark. We're all up here or we're all down there, or we're kind of

right in the middle, and that's all you're saying.

PANEL MEMBER WILSON: What would that benchmark be in the NHANES data?

PANEL MEMBER McKONE: I would say median, but if there's some -- there might be some reason. I wouldn't want to lock -- you know, say, walk away saying you have to use the 50th percentile. I think I would give the staff a lot of latitude to figure out what's a reasonable benchmark to use within the limit of detection.

Right now, we've used the limit of detection. And everything is above the limit of detection, so that's not informative -- or not every, but most of it is. So that's not informative anymore, so you'd like to pick some other anchor point that would help you see, oh, well, here's how it compares to another benchmark.

CHAIRPERSON LUDERER: Dr. Fenster.

DR. FENSTER: I've been asked just to convey questions for clarification for the staff. As many of you have known that have compared data to NHANES, we would be -- usually, there's a lot of discussion about which years to use in these studies. The aggregate table combined data from 2005 through 2010.

So, you know, basically we may have follow-up questions as to what years to be choosing the reference data, and we also have children through adults. So again,

typically, we try and find the NHANES population that is most comparable to whatever study we're doing. So we face challenges and we may just come back to you and ask your input when we're trying to proceed. If you have any suggestions now.

PANEL MEMBER WILSON: I guess one of the -- I mean, one of the issues here is who the audience is. And if the audience, in particular, is members of the Legislature and reporting on progress under the Program and so forth, it's probably helpful not to get into a large amount of detail and discrimination around the different findings and so forth. And that reporting a detection frequency in some measure of -- I think, you know as we're suggesting here, some basic measure of comparison with NHANES where we can, and keeping it fairly simple, is a useful thing. Also, recognizing that it has a lot of limitations.

But it feels to me like we're sort of trying to parse something that's scientifically sound, but also -- but against something that's sort of a message that can be delivered to a fairly distracted legislative body. You know, so there's sort of two things we're trying to reconcile here it seems.

CHAIRPERSON LUDERER: Sara

MS. HOOVER: Hi. Sara Hoover, OEHHA.

Yeah, we really appreciate all this feedback. And given the short time, what I'm wondering is kind of following on what Laura just asked, if we could identify maybe one Panel member who we could go back to with some of these detailed questions, because a lot of the suggestions that were made we've spent months kind of going through them, and looking at them, and trying to figure out.

And so we brought it to the Panel for your input. But if we pursue them, we'll probably have follow-up questions. So if there could be one Panel member -- we can't have a group, obviously, because of the Bagley-Keene limitation. But if there's one Panel member who could volunteer to be a sounding board as we go through these issues, that would be really helpful. Then we could move on to the other questions and continue the discussion questions.

CHAIRPERSON LUDERER: Is it permissible to have two Panel members? We have a question from the Panel.

CHIEF COUNSEL MONAHAN-CUMMINGS: (Nods head.)

MS. HOOVER: Carol, our legal counsel, says, yes, it's permissible to have two.

CHAIRPERSON LUDERER: Do we have volunteers from the Panel?

Dr. McKone, are you volunteering?

PANEL MEMBER McKONE: I will.
MS. HOOVER: Great.
CHAIRPERSON LUDERER: And Dr. Solomon.
MS. HOOVER: Okay. Great. Thank you very much.
CHIEF COUNSEL MONAHAN-CUMMINGS: That was an informal discussion and an informal designation, right, you weren't formally designating a subcommittee, correct?
CHAIRPERSON LUDERER: Correct.
(Laughter.)
CHAIRPERSON LUDERER: So we need to move on to some of these other discussion questions, since, I guess, we only have 10 minutes allotted, and there's still quite a bit to discuss.
Dr. Solomon, you earlier had said that you wanted to make a comment on one of the other discussion questions. Which --
PANEL MEMBER SOLOMON: Sure. And just to go back quickly to the last one. I think what may have been reflected in the discussion that just happened is a little bit of like, you know -- I mean, I know from my perspective that I felt like I wasn't quite seeing enough information to feel satisfied in that table. And that just may be the way it's going to have to be.
What I was -- I'm encouraging the staff to do is to sort of look at ways -- at the possibility of figuring

out, you know, is it possible to provide a little bit more flesh, a little more information to make that table feel more satisfying. And it may not be really doable within the current time allotted to get this report finalized.

And if so, then perhaps something such as what Dr. Kavanaugh-Lynch suggested, which would be, you know, pulling out a couple of little examples and fleshing those out, instead of trying to, you know, do a lot more number crunching and expand the table. That actually could provide that sort of sense of greater satisfaction of the data.

So I think there are various ways that would all be okay for moving this forward. It doesn't have to be, you know, going with that 50th percentile of NHANES, though was -- I liked the suggestion.

So going to the other one, the three main message content. So I really like numbers one and two. And I'm sympathetic to number three, which was that Biomonitoring California has leveraged limited State resources through successful collaborations, though my concern is it sounds a little bit -- I don't know. It sounds a little bit like you're sort of trying to make a political more than a scientific point with that. And it just -- it makes me a little nervous.

And in some ways, some of the things that are

buried below that bullet or headline might be even more exciting to people. You know, that the Program has studied more than 10 populations across California, including pregnant women, firefighters, residents of agriculture communities, and pre-adolescent girls.

I could actually see moving that phrase up into the header, and putting the leveraging limited State resources into the paragraph below, because I think it's huge that we've, you know, studied pregnant women, firefighters. You know, all of these different populations are -- you know, should be up in lights from my perspective, and they're sort of buried right now.

DR. DAS: That's a great suggestion. Thank you.

CHAIRPERSON LUDERER: Comments from other Panel members regarding this question about the main messages.

Sara.

MS. HOOVER: I just had a follow-up question, because of the earlier comments that I thought were very interesting about trying to provide some context about -- we've looked for and found in some messaging around this is not -- it's not representative of a lot of things, including possibly what's actually in our bodies, necessarily. So I'm wondering if that might be a message that we should think about commenting on in some way in the report, following back to those earlier comments.

CHAIRPERSON LUDERER: Dr. Wilson.

PANEL MEMBER WILSON: Thank you. I agree with that. I mean -- and also agree, you know, with Dr. Solomon's comment. I think that it is exactly right to be flipping that paragraph. But it's something, from what I'm hearing you say and I think it makes sense, to say something about we've captured some piece of the universe, but here are the limitations. Just to put it in that context, I think would be a helpful addition here.

CHAIRPERSON LUDERER: I'm wondering whether perhaps it would be helpful for you to clarify, or are you thinking of clarifying it within the second bullet point or adding another point about that.

PANEL MEMBER WILSON: Yeah. I think it probably could be within one of these paragraphs, because paragraph two or three, in that, you know, we can -- for example, in paragraph two, we can now analyze approximately 100 different chemicals in blood or urine, and also in paragraph three about the 10 populations. So a sentence that says something to the effect of -- that sort of answers this question in people's minds of, oh, did we take a sample of blood and screen for 80,000 chemicals and this is what we found, or this is what we looked for and this is what we found. That seems to be an important piece of information for people to interpret --

interpreting these findings.

DR. DAS: Right. I think Dr. McKone had brought up that issue in the past. So we can incorporate it into one of these paragraphs.

CHAIRPERSON LUDERER: Dr. Solomon.

PANEL MEMBER SOLOMON: Well, if we're going on to other questions, the next set of questions on Slide 21, I actually think -- I think the groupings of chemicals are relevant -- are fairly useful and understandable. I can't think of a better way to do it. I mean, it's going to be a little technical for some audiences, but I'm not sure there's any way to fix that that I can think of.

I think that information on method detection limit and all of the technical aspects, at some point, it would be nice to have something like that as an on-line appendix, where there would be a link in a document like this for people who want to then click on that and get a more technical document that has all of that information in it. I don't know that that needs to be prioritized and done immediately, but it should be done at some point.

And then I love Figure 1. Figure 1 is a, "Wow". You know, an, "Oh, my God. I can't believe this". So I think that's something that we need to -- you know, that should be like very strongly highlighted with every audience and every presentation that's out there, because

it shows this fantastic progress.

DR. DAS: I wanted to acknowledge that Figure 1 was Amy Dunn's brainchild. So I thank her for it.

(Applause.)

CHAIRPERSON LUDERER: Dr. Kavanaugh-Lynch.

PANEL MEMBER KAVANAUGH-LYNCH: I'm partly holding back, because I'm like -- we can word-smith, and that would not be particularly helpful. But I've decided this maybe warrants being said.

So just based on what the comments that have been said thus far, there are a couple things I could see doing in here. One is incorporating the suggestion about "have looked for and found" into the wording of the first message. That seems to me a good place to do that.

And then when they -- in the second paragraph describing the second message that the Program's laboratories can now analyze approximately a hundred different chemicals. You know, a hundred different chemicals that have been prioritized as of potential concern to the people of California. You know, something to say not just any hundred, but a hundred that we carefully chose for reasons.

And then the last thing is possibly also incorporating that concern about what are we missing out on by only looking at these 100. With Gina's suggestions

for the future and the like potential of in the future looking -- screening for unknowns. That, you know, somehow incorporating that, you know, the 100 -- among the hundred that we think are important, as well as developing methods for looking for things we don't know are important yet. And I stop wordsmithing.

Thank you.

DR. DAS: Thank you. Those are really important suggestions. Thank you for those.

CHAIRPERSON LUDERER: Dr. Alexeeff.

OEHHA ACTING DIRECTOR ALEXEEFF: George Alexeeff.

Yeah, I just wanted to add. It might be useful to, at some point, refer to the NAS document that was talking about biomonitoring, and the importance of building infrastructure within the States for lots of reasons. And, although, this is great, we're biomonitoring, but there's other reasons we need to have a very strong ability to do this in terms of for, you know, other reasons, you know, terrorism, whatever, that kind of stuff.

So I think that's something that maybe we could look at the NAS document and have some simple statement saying that we're moving along the importance of building the infrastructure as suggested by the Academy of Sciences.

PANEL MEMBER SOLOMON: I'd strongly endorse that. This is Gina Solomon.

CHAIRPERSON LUDERER: I would as well.

Dr. Wilson.

PANEL MEMBER WILSON: Just a small point about occupational exposure limits, that I would be a little bit concerned about comparing any of these findings to occupational exposure limits, in part because, you know, there's so -- you know, choosing the -- you know, which one we're going to use. But the OELs are just so antiquated in so many ways, that I would -- it just -- it seems like an artificial comparison to me.

And so I guess I would have some concern about putting those in. And I think I'd heard on the Panel somewhere that -- or a suggestion that we do that. Was that --

MS. HOOVER: No.

DR. DAS: No, I think I mentioned that cadmium has a biological exposure index, which is used for occupational purposes, but we wouldn't necessarily put that in the document.

PANEL MEMBER WILSON: Okay. Thank you.

CHAIRPERSON LUDERER: Dr. Culver.

PANEL MEMBER CULVER: Since occupational exposure limits has come up, maybe there's a little something that

we can draw from our understanding of occupational exposure limits.

There are variously estimated to be 60,000 to more than 100,000 different chemicals that are used in industry today. And, yet, we have occupational exposure limits to only about 500, but -- and everybody cries doom and horror that we don't have more exposure limits in view of the massive numbers of chemicals that exist in industry.

I'm on an agent -- or an organization that sets occupational exposure limits. And we're having a hard time finding what other chemicals that are used in industry we should be writing exposure limits for. There's a kind of a natural process that causes us to think that an exposure limit is needed, and versus the amount of difficulty in coming up with an exposure limit, so that it's the -- it's big chemicals in industry and they're not all that many. It's the chemicals that are -- have lots and lots of people exposed. But again, there are not that many.

So there's a natural process that I think will also go on in our attempting to identify chemicals that should be listed, that is, I think, already in operation. We are already hitting the important ones, and we're going to have more and more difficulty identifying which others

have that level of importance. I just thought that's an interesting possible simile that I'd like to call the Panel's attention to.

CHAIRPERSON LUDERER: Do we have any other comments, points of discussion on these questions from Panel members. And also I wanted to ask the Program staff whether there's anything in particular that you feel we have not hit on in our discussion that you would like us to.

DR. DAS: The next.

MS. HOOVER: The next question.

DR. DAS: Yeah. I don't think we've addressed all of the questions. I think Dr. Solomon did address this question about Table 1 and Figure 1, but I didn't hear input from others on this. And then this question about the project collaborations with regard to the data summary report, and the public release, whether there was any input on that.

CHAIRPERSON LUDERER: Any comments, responses on that from Panel members?

I mean, I might just add regarding the Figure 1, I completely concur that that's wonderful and definitely want to keep that and not make changes, I think.

Other comments or questions from Panel members about this particular question, which we really haven't

discussed, about the collaborations and the level of detail?

DR. DAS: I did hear one suggestion from Dr. Wilson, which was to specifically mention the Orange County Fire Authority. I wasn't sure if you meant within the context of FOX.

PANEL MEMBER WILSON: Thank you. Yeah, definitely within the context of FOX, but it wasn't the Orange County Fire Authority, but the firefighters union that participated.

DR. DAS: Oh, the Orange County Fire Authority Oversight Committee actually is the entity that we collaborated with. And the oversight committee consists of labor and management together. We certainly did interact with the union, but I would say it was more the Orange County Fire Authority Oversight Committee, which is the joint labor management team that we participated with.

PANEL MEMBER WILSON: I think that's an important distinction actually to call out, that the joint labor management -- it can be described as the joint labor management Orange County Fire Authority committee --

DR. DAS: Oversight Committee.

PANEL MEMBER WILSON: Oversight Committee. It's important for the people who I work -- I'm working with that are union leadership and so forth, to know that this

was a collaborative project, that -- you know, that involved the membership and so forth.

DR. DAS: Certainly. I agree with you. And the point that's important is that it was a labor management team that we've worked with, and so we'll include that information.

PANEL MEMBER WILSON: That's great. Thank you.

CHAIRPERSON LUDERER: And I think that the level of information that's provided in the tables is quite useful. And I think it really captures the diversity of these different populations, and nicely shows how all the different groups of chemicals that have been biomonitored in those populations, as well as the geographic distribution of where the populations come from. And then the paragraph format describing what the different studies were, I think, the level of detail for me, I think, is sufficient.

Do any of the other Panel members have additional comments about that, disagree, agree?

Dr. Wilson.

PANEL MEMBER WILSON: Yeah. I guess I'm wondering if it would be, looking at Table -- I guess, are we on Table 2? Did we look at Table 2? Yeah.

The, you know, chemicals being biomonitored if it's -- if it would add too much noise to put the

percentage -- you know, identified next -- you know, in each of the columns. So within each of those, you know, within each of the projects.

So for the BEST study, it would say PBDEs and a column next to it, it would be a split column. It would say detected or it would be biomonitored, and then the next column next to it would be percent detected. Is that --

DR. DAS: Okay. Are you suggesting that there's a combination of Table 2 and 3 then in one table?

PANEL MEMBER WILSON: Well, I'm asking a question. If that's going to generate too much noise or if that's...

DR. DAS: Yes. The issue there is that that would be -- that's a way of presenting individual study information. So I think at the point that we feel we've conducted enough analyses to present individual study information, we would choose to do that in an understandable format.

But I think the way you're suggesting it is presenting individual study information on top of the information that's presented in Table 2.

PANEL MEMBER WILSON: And we don't have that information yet, is that the point?

DR. DAS: For BEST we don't.

PANEL MEMBER WILSON: Right.

DR. DAS: Yeah. We do for some studies, but we -- as we've been talking awhile, we've presented aggregated data so far. Although, we do plan to present individual study information. At that point, I think we'll pull out the information that's meaningful and present the study on its own.

PANEL MEMBER WILSON: Yes. Okay. Thank you.

CHAIRPERSON LUDERER: All right. I think if we have no more comments from panel members, and since we are a little bit behind our schedule, then we'll move on to the next presentation.

So I'd like to introduce Dr. Gail Krowech, staff toxicologist at OEHHA, who will present a non-halogenated aromatic phosphates for consideration as potential designated chemicals.

Dr. Krowech.

(Thereupon an overhead presentation was Presented as follows.)

DR. KROWECH: Good afternoon. Okay. I wanted to start out by reminding everyone what designated chemicals are. Designated chemicals can be considered by -- are chemicals that can be considered for biomonitoring. And they are chemicals that are part of the CDC's National Reports on Human Exposure to Environmental Chemicals

Program. The Panel can also recommend additional designated chemicals for inclusion in the program using specific criteria, which I'll go over in a moment.

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DR. KROWECH: First, I wanted to briefly provide some background on how we came to be looking at non-halogenated aromatic phosphates. Triphenyl phosphate was presented as one possible plasticizer to investigate for designation at a Panel meeting in November 2010. And at that meeting, the Panel was most interested in our following up on organophosphate plasticizers and flame retardants.

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DR. KROWECH: The Program presented a screen of organophosphate -- non-halogenated organophosphate flame retardants at the March 2011 Panel meeting. And at that meeting, the Panel requested that the Program prepare a potential designated document on non-halogenated aromatic phosphates.

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DR. KROWECH: This slide shows the criteria for the Panel to recommend designated chemicals. They are: exposure or potential exposure, known or suspected health effects, the need to assess the efficacy of public health actions, the availability of a biomonitoring analytical

method, the availability of adequate biospecimen samples, the incremental analytical cost.

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DR. KROWECH: A number of agencies are concerned about aromatic phosphates because of their growing use. And I will be talking about some of them in a few minutes.

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DR. KROWECH: First, I just wanted to say something about the structures. This right here is a triphenyl phosphate. The phosphate in the middle, and aromatic -- the three aromatic rings. For tricresyl phosphate is an example of an aromatic phosphate with a substituent on the aromatic ring. And this could be -- in this case, it's a methyl group, but it could be branched. And here's one final example showing that it doesn't have to have three aromatic groups. This case there are two aromatic groups. It's a diphenyl phosphate.

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DR. KROWECH: Here are two more structures. This first one, as the name implies, has a bisphenol A center. And it is joined by diphenyl phosphate at the two hydroxyl groups. And this one is resorcinol bis(diphenyl phosphate). The same idea with the two diphenyl phosphates at the hydroxyl groups.

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DR. KROWECH: This slide shows some uses of flame retardants -- uses as flame retardants in plasticizers. This group is used for polyvinyl chloride and other plastics. It's uses in consumer electronics. It's used in polyurethane foam, in textiles as backcoating and artificial leather, in paints and varnishes and in hydraulic fluids.

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DR. KROWECH: And this slide shows some examples of flame retardant plasticizers of use as flame retardants in -- not as plasticizers in plastics. Some of these aromatic phosphates are used -- are being used as replacements for deca-BDE, which is being phased out. In the plastic housing for televisions, and those are bisphenol A bis(diphenyl phosphate), resorcinol bis(diphenyl phosphate) and triphenyl phosphate are all major use -- phosphates used for this purpose.

There's also a lot of use of aromatic phosphates in computers, in screens, keyboards, printers, in the mouse. And triphenyl phosphate is probably the most frequently found of these, but tricresyl phosphate has also been found in consumer electronics.

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DR. KROWECH: Another use of aromatic phosphates is in polyurethane foam. The U.S. Consumer Products

Safety Commission staff had concerns about the increasing use of aromatic phosphates, and recommended them -- six representative aromatic phosphates to the NTP for testing.

These three aromatic phosphates here have been found in polyurethane foam. The first two isopropylated triphenyl phosphate and triphenyl phosphate are contained in Firemaster 550, which is a primary replacement for penta-BDE as a flame retardant in polyurethane foam, and butylated triphenyl phosphate has been found in polyurethane foam as well.

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DR. KROWECH: Here's the uses of plasticizers. The structure here is ethylhexyl diphenyl phosphate. And it's been -- it's approved for use in food contact packaging. It's been used for a long time. And here I'm just giving some examples of levels of ethylhexyl diphenyl phosphate that have been found in food.

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DR. KROWECH: This slide shows some other household and consumer uses in curtains, upholstery fabric, wallpaper and nail polish, dog flea colors, biogradable(sic) tampon ejectors, tubings for skinless sausages.

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DR. KROWECH: This slide just shows levels of two

of these aromatic phosphates in house dust, triphenyl phosphate and tricresyl phosphate. The triphenyl phosphate is shown for two studies, one in Belgium and one in Boston in the U.S., Boston, Massachusetts.

The important thing about the study is that detection frequency, it's almost always found. You can't really compare these two studies, so this slide just represents examples of levels that have been found.

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DR. KROWECH: And another study looking at house dust, this one from a study in Sweden. And they compared home, office, and day care, 10 homes, 10 offices, 10 day cares for -- and two aromatic phosphates were looked at here. And one of the things to note is looking at triphenyl phosphate, the levels are much higher in offices than homes, and that probably reflects use in electronic equipment and computers.

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DR. KROWECH: This slide shows a comparison of flame retardants in house dust. It looks at triphenyl phosphate compared to TDCPP, which is one of the primary replacement flame retardants for penta-BDE in polyurethane foam. And it also has two penta -- two PBDE congeners from the penta-BDE mixture that were used in polyurethane -- that are in polyurethane foam, probably in

most houses still. And you can see that the levels of triphenyl phosphate are high compared to these.

And if you convert this to moles and look at in terms of moles instead of mass, it's even higher.

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DR. KROWECH: In terms of known or suspected health effects, the amount of toxicity information that was located varied widely among the aromatic phosphates that were highlighted in the document. And as we always note, we did not conduct a thorough literature review for this document.

In the document, we also included some information submitted under the REACH Program, but here I'll be providing you with a sample of known or suspected health effects, largely based on the published literature. And I'm not going to be presenting everything that was in the -- each of the chemicals that were highlighted in the document, but just a few of them.

So for the first example bisphenol A bis(diphenyl phosphate). The concern is possible metabolism to bisphenol A and/or bisphenol A diphenyl phosphate. So that would be a loss of one of the diphenyl phosphate moieties, and the biological activity of that molecule isn't known.

For butylated triphenyl phosphate, this

chemical -- this -- well, it's a group isomers. Butylated triphenyl phosphate is on Grandjean and Landrigan's list of chemicals known to be neurotoxic to humans. It's also reported as reproductive -- to have reproductive toxicity at high doses. As I said, this is a mixture of isomers. And one of those isomers is t-butylphenyl diphenyl phosphate, which was included in the document.

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DR. KROWECH: Isopropylated triphenyl phosphate is also a mixture of isomers. And U.S. EPA in a hazard characterization document for the High Production Volume chemicals program reported its neurotoxicity in hens. In vitro it's shown an effect on human androgen receptor activity. Several of the isomers have shown an effect, and they've either increased or decreased the activity depending on the position of the isopropyl group.

And almost all of them activate two human nuclear receptors that are important in the expression of specific drug metabolizing enzymes, such as cytochrome P450.

Tricresyl phosphate is the one aromatic phosphate that has been studied most, and most information is available about it.

The O of cresyl phosphate -- o-tricresyl phosphate is neurotoxic. And under current production methods only para- and meta-tricresyl phosphate isomers

are produced. The ortho-tricresyl phosphate is reported to consist of less than 0.1 percent.

Tricresyl phosphate is also -- has also shown reproductive toxicity, including decreased fertility and effects on the testes and ovaries. It's the only aromatic phosphate that has had an adequate carcinogenicity study. It was negative in this bioassay. But the study found effects in the adrenal cortex, which had suggested changes possibly in steroid metabolism.

In in vitro studies, one of these isomers, P-tricresyl phosphate also activated the two human nuclear receptors mentioned above.

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DR. KROWECH: For triphenyl phosphate, levels in house dust were associated with a decrease in sperm concentration and an increase in prolactin levels in a study of 50 men recruited from an infertility clinic. Triphenyl phosphate is also on Grandjean and Landrigan's list of chemicals that are neurotoxic to humans.

In vitro, triphenyl phosphate decreased the activity of the human androgen receptor in one study. In another study, it showed moderate binding to the androgen receptor. And it also increased the activity of the two nuclear receptors, CAR and PXR.

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DR. KROWECH: As I mentioned, the staff from the Consumer Products Safety Commission recommended non-halogenated aromatic phosphates to NTP. NTP approved the request, and they have planned studies, in vitro studies on six representative aromatic phosphates. They'll be studying neurotoxicity, reproductive toxicity, effects on liver enzymes and steroidogenesis.

NTP also plans two in-depth in vivo studies -- plans in vivo -- in-depth in vivo studies on two aromatic phosphates. One of them will be triphenyl phosphate and another will be a branched aromatic phosphate. And they will be studying both in rats and mice. They'll be looking at neurotoxicity, immunotoxicity, and reproductive and developmental toxicity.

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DR. KROWECH: In terms of the physical chemical properties of this group, for most of the aromatic phosphates the pure chemical is not evaluated, so it's very difficult to sort all of this out. Many of the chemicals were contaminated with triphenyl phosphate. Others were components of the mixture or mixtures of isomers. And so there were multiple values in the literature for just about everything.

And just as an example, there were a range of vapor pressures identified. This one for bisphenol A

bis(diphenyl phosphate). The estimated values varied about 10-fold.

Again, the octanol-water partition coefficient was affected by contaminants or other components in the mixture, so it wasn't always clear. But for most of the compounds that were highlighted in the document, the log K_{ow} was greater than 4.

And just to provide context for these numbers, log K_{ow} of greater than 4 is regarded as evidence of bioaccumulation potential.

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DR. KROWECH: This slide shows persistence predictions using EPA's screening tool PBT Profiler. And as you can see, most of the aromatic phosphates are very persistent in sediment and persistent in soil.

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DR. KROWECH: There is evidence of bioaccumulation in -- for two aromatic phosphates. Triphenyl phosphate has been found in bottlenose dolphins, and fish and in bivalves. Ethylhexyl diphenyl phosphate was found in fish. The bottom of this slide shows bioconcentration factors for some of the aromatic phosphates. And these also varied widely in the literature, but this is just a sampling of the range that was found. And again, for context, BCF greater than 1,000

is regarded as evidence of bioaccumulation potential.

And I just maybe would note that the BCF value for triphenyl phosphate is 420 here. Yet, it was found in biota.

In terms of pharmacokinetics and metabolism, from what we know so far there seems to -- it seems to suggest that these aromatic phosphates are absorbed orally. Urinary metabolites have been identified for some of the chemicals. For some, no information was located on metabolism or excretion.

The route of excretion could depend on the isomer. For example for tricresyl phosphate, the ortho isomer is excreted primarily in urine. The meta-isomer is excreted in feces. And the para-isomer is excreted in urine at low dose, and at higher doses is excreted in feces.

Both triphenyl phosphate and ethylhexyl diphenyl phosphate were detected in breast milk. And more research is needed to determine which phosphates would be found in urine or blood.

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DR. KROWECH: A few biomonitoring studies were located. There are two recent studies that found the triphenyl phosphate metabolite, diphenyl phosphate, one from the United States, and one from Germany.

And a study in Sweden reported finding both triphenyl phosphate and ethylhexyl diphenyl phosphate in pooled breast milk samples.

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DR. KROWECH: In terms of the laboratory analysis, Biomonitoring California would need to adapt or develop -- adapt and develop analytical methods. Methods for analysis of diphenyl phosphate in urine are available in the literature.

One difficulty is that reference standards are available only for a few of the aromatic phosphates. Analysis of non-halogenated aromatic phosphates could likely be bundled.

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DR. KROWECH: In terms of the need to assess the efficacy of public health actions, there's widespread and probable increasing use of non-halogenated aromatic phosphates. I didn't, in this presentation, mention production volume in the U.S. before, but all of these are High Production Volume chemicals. Some are -- several are in the range of 10 to 50 million pounds reported in 2006.

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DR. KROWECH: And in this last slide, we laid out some options that the Panel might wish to consider in their discussion. The Panel could consider recommending

that the class of non-halogenated aromatic phosphates be added to the list of designated chemicals. You could consider recommending that one or more individual chemicals be designated. I've also noted that there will be results coming for some of these chemicals from NTP studies, and there will likely be other information coming out. So you might chose to delay making any recommendations. And finally, you could also recommend against designating these chemicals.

And now I'll be happy to answer any questions about the presentation.

CHAIRPERSON LUDERER: Thank you, Dr. Krowech and for preparing this excellent document in response to previous requests by the Panel. A lot of really detailed information about these different chemicals.

Do any of the Panel members have comments, questions?

Dr. Solomon.

PANEL MEMBER SOLOMON: Yes. Thanks. This is a great presentation and a very, very nicely done briefing packet. Thank you.

My question is just to probe for a little bit more information about the list that you chose, which includes eight of these aromatic phosphates versus the list that the Consumer Products Safety Commission proposed

and the NTP is proceeding on, that six out of these eight. Was there -- you know, can you provide sort of any additional information about why CPSC limited their list to six at -- and, you know, and some of the information that motivated you to add the additional two.

DR. KROWECH: What I can say about CPSC is I think -- and my understanding was, they were just representative. So it wasn't that they were particularly targeting these. I think they were -- they were looking at it as these are some that may be up and coming, have increasing use in foam and in textiling, and backcoating of furniture.

And three of them have been identified in foam. So this is pretty much what I know, but I don't think it was meant to be a definitive list. It was basically as a representative sample. And in terms of what they're choosing, so they want to look at what the effect. They want to look at triphenyl phosphate, and then the effect of an aromatic phosphate that adds other components.

In terms of why I added the other two, because they're also aromatic phosphates. And I think their disposition in the body is really unknown, and it seemed just fitting to me that if we were going to look at non-halogenated aromatic phosphates, we might include them all.

CHAIRPERSON LUDERER: Dr. McKone.

PANEL MEMBER McKONE: Thank you. That was a really informative presentation. I think it's useful for us. I guess -- again, this is a comment probably as much as a question. But I know long ago we talked about selecting chemicals where we might see a large change in pattern. And that Biomonitoring Program offered an opportunity to look at what's happening in the market. And, you know, it sounds like these are chemicals -- some of these are really growing rapidly. They're entering the market at a very rapid rate in large volumes, particularly substitute flame retardants.

So if this could be couched -- I guess the question is, can this be couched in a way or set up in a timely way, so that we can actually watch the levels either change or not change in the population as the use patterns grow, you know, because we have market information at the same time we have biomonitoring information.

So I think that opportunity is there. I suppose you can call that a question or a comment.

DR. KROWECH: Thank you for the comment.

CHAIRPERSON LUDERER: Other clarifying questions from Panel members. We have a public comment period coming up, and then we have more time for discussion among

the Panel.

Do we have any public comments from public present here?

Okay. And we don't have any by email on this topic.

So then we can move on to our discussion. So really what we're discussing then is whether we, as a Panel, feel that we should consider designating these non-halogenated aromatic phosphates as a class or whether we would like to defer that until later when there's more information available, such as from those NTP studies that were mentioned, or we could also decide against designating.

Are there any thoughts from the Panel about these different options?

Dr. Wilson.

PANEL MEMBER WILSON: Sure. You know, my sense in -- you know, from the presentation -- thank you, Gail -- and also in reading your briefing document, is that we have sort of a portfolio of problems that, you know, suggest to me that this is a class of chemicals that should be designated. And those -- that portfolio is the fact that they're emerging as the substitute for substances that California has identified as problematic, being the brominated flame retardants. So they're

emerging as commercially important in California, probably uniquely in the U.S. as a consequence of Technical Bulletin 117.

They're problematic with regard to both persistence and bioaccumulation. And they're problematic on the hazard side as well, as I remember from the briefing document, also from, I think, as Gail mentioned hormone disrupting or interrupting effects and so forth.

So I guess my tendency is to lean toward designating these non-halogenated aromatic phosphates as a class for biomonitoring.

CHAIRPERSON LUDERER: Other comments from Panel members?

Dr. McKone, from your earlier comment, was that the direction that you were also headed in?

PANEL MEMBER McKONE: Yeah. I would move my earlier comment forward to this discussion, which is -- I mean, there are a number of compelling cases, I think, here, but probably seeing something that really meets a lot of -- I mean, by any sort of chemical hypothesis, we should find these they're persistent, very persistent, by certain criteria. They're rising in use. They're likely to be a major substitute for anything that is removed from the market, the brominated flame retardants. These are problem going to enter unless somebody removes the

technical bulletin that requires those, which seems unlikely.

So I think it's an opportunity for us to really watch something happening and see -- and learn about whether there are mitigations or what the sort of dimensions of it are. So it's a very important opportunity, both in terms of protecting health, if that's needed, or anticipating health problems, but also in terms of biomonitoring research. These are certainly the types of chemicals that make sense to put into a biomonitoring list -- I'd be -- you know, I would also move to put them forward on the list.

CHAIRPERSON LUDERER: Any other comments from other Panel members?

Dr. Solomon

PANEL MEMBER SOLOMON: I'm very pleased that the NTP will be studying these chemicals. And, you know, while it's sort of tempting to wait and see what the NTP finds, that sort of perpetuates the problem that I see of waiting until you have clear toxicity data before starting to assess exposure, and sort of always putting the exposure as a sort of an afterthought. Exposure considerations, in my view, should operate in parallel with toxicity evaluations.

And so I think there's some significant merit to,

you know, starting to explore human exposures while the toxicity evaluation is still underway, if we believe that the -- you know, that the set of chemicals meet the criteria that are before us. And, you know, looking at the criteria, I think that there's ample information in our packet to indicate a potential exposure to the public, not a lot of data on actual exposure. But we certainly just on the basis of persistence, bioaccumulation potential, wide spread use, and some exposure data that do exist, I think we meet that criterion.

On known or suspected health effects, there are, you know, certainly pretty good information on neurotoxicity and some very interesting and worrisome information on endocrine effects for a number of these chemicals. And so I think that, you know, as a group, although we still have huge data gaps, have enough -- you know, certainly the same information that drove NTP to take this on as a high priority for their resources, gives us, you know, similarly some reason to prioritize these.

And then as Dr. McKone mentioned, you know, very compellingly there is the need to assess the efficacy of public health actions to reduce exposure, and then the flip side of that, which is the potential for -- you know, associated potential for increased exposure due to various actions, such as flame retardancy standards.

We, at this point, really do not need criterion for the availability of biomonitoring analytical method yet for many of these chemicals, though it's meant for some of them. And, in my view, that's something that, you know, needs to be investigated by the laboratory. But we have previously, as a Panel, listed chemicals -- designated chemicals for which no biomonitoring analytical method yet existed, and the laboratory has been fantastic at rising to those challenges. And we certainly do have a availability of adequate biospecimen samples. The incremental analytical costs obviously is a consideration here. But as indicated, these could be quite likely bundled.

So I think we're there, in terms of meeting the criteria for designating these chemicals as a group. And I am leaning toward doing that. I, you know, I recognize that at least one of them, the bisphenol A bis(diphenyl phosphate), it may well be that that's sort of moot, because the main chemical that would be biomonitored there would be bisphenol A, which is already a priority chemical and is already being biomonitored.

With that, you know, I guess there's no harm done in sort of doubling up there, the marker -- the biomarker might end up being one we already have.

CHAIRPERSON LUDERER: Dr. Culver.

PANEL MEMBER CULVER: Just a question. Are they -- do they all have about the same amount of bioavailability?

CHAIRPERSON LUDERER: Dr. Krowech, would you like to address that.

DR. KROWECH: I think the answer is we don't really know from -- because we don't know the metabolites and we don't know the excretion. So we don't really know for all them. They haven't been studied. At least one of them is primarily excreted in feces, so I'm not sure if that would actually be able to be detected, but that would also have to be investigated.

CHAIRPERSON LUDERER: Dr. Wilson.

PANEL MEMBER WILSON: I just have a clarifying question for Dr. Krowech. If the samples -- pooled samples from breast milk in Sweden. Did that information show trends over time for the triphenyl phosphate?

DR. KROWECH: I would have to go back and look at it. I'm not sure. But there were -- it was from probably a period of 15 years, at least 10 to 15 years where there were pooled samples. I'm tending to think no, but I'll check on it and let you know.

PANEL MEMBER WILSON: Thanks.

CHAIRPERSON LUDERER: Dr. Solomon.

PANEL MEMBER SOLOMON: Just a quick addendum

that -- in terms of the fact that some of these chemicals, especially I think the two ethylhexyl diphenyl phosphate in humans at least appears to be mostly excreted in feces, that, to me, does not necessarily indicate a lack of absorption, because obviously many chemicals of this nature that are actually absorbed are excreted through bile, and therefore end up in feces, even though they actually are absorbed into the body.

DR. KROWECH: I agree. I didn't mean to say that they weren't absorbed, but that I didn't think they -- I guess I was answering the question in terms of whether or not they could be biomonitored. But ethylhexyl diphenyl phosphate is one that has a -- it's almost, I think, 40 percent excreted in urine. So it was the resorcinol bis (diphenyl phosphate) that is excreted primarily in feces.

CHAIRPERSON LUDERER: All right. We've heard comments from several Panel members. And my summary of what we've heard so far is that it seems that we have an emerging consensus regarding designating these non-halogenated aromatic phosphates as a class. Any disagreement with that interpretation among the Panel members?

And, Dr. Wilson, did you have a comment?

PANEL MEMBER WILSON: Would you entertain a motion?

CHAIRPERSON LUDERER: Yes, I would.

PANEL MEMBER WILSON: Then I would move that the Panel designate non-halogenated aromatic phosphates as a class for biomonitoring in California.

CHAIRPERSON LUDERER: Okay. Is that a second, Dr. McKone?

PANEL MEMBER McKONE: I'll second that

CHAIRPERSON LUDERER: All right. So then shall we start with Dr. Kavanaugh-Lynch and the Panel can vote.

PANEL MEMBER KAVANAUGH-LYNCH: Yes.

PANEL MEMBER CULVER: In favor.

PANEL MEMBER McKONE: Yes.

CHAIRPERSON LUDERER: Yes.

PANEL MEMBER WILSON: Yes.

PANEL MEMBER SOLOMON: Yes.

CHAIRPERSON LUDERER: All right. The Panel unanimously voted in favor of designating non-halogenated aromatic phosphates to the California Environmental Contaminant Biomonitoring Program.

All right. Yes, we are a little bit ahead of schedule actually, at this point. So we can take a -- the next item on the schedule is a break. So should we take 15 minute break. So we'll be back at 3:20.

(Off record: 3:06 p.m.)

(Thereupon a recess was taken.)

(On record: 3:25 p.m.)

CHAIRPERSON LUDERER: All right. I'd like to call us back to order here. If everybody could please take a seat. Welcome you all back.

And I'd like to go ahead and introduce Sara Hoover, who is the Chief of the Safer Alternatives Assessment and Biomonitoring Section of OEHHA.

Sara.

MS. HOOVER: Thank you. So the last presentation of the day. This is on chemical selection planning. And I'm going to be introducing Laurel Plummer as part of this item as well, who is our new Associate Toxicologist.

(Thereupon an overhead presentation was Presented as follows.)

MS. HOOVER: So the purpose of this agenda item first is that we're going to be talking about a preliminary screen that we did for possible future consideration as potential designated chemicals - it's quite a mouthful - regarding some bisphenol A, BPA substitutes, and structurally related compounds.

So here I want to really acknowledge Dr. Laurel Plummer, who's here in the room, front row. She started in my section as an Associate Toxicologist in December. She earned her BA from UC Santa Barbara, where she majored in environmental studies, with an outside concentration in

organic chemistry. She received her Ph.D. in 2011 from UC Davis working with Dr. Kent Pinkerton. And the focus of her research was on looking at the association of particle size, season and source with pulmonary and cardiovascular health impacts of ambient particulate matter in San Joaquin Valley. And she recently presented her research at the Society of Toxicology meeting.

So Laurel has been an enormous help conducting toxicological research for the Biomonitoring Program, for our portion of it in OEHHA. And she's also going to be taking over for me as the primary coordinator for the SGP Panel meetings. So, everyone, please welcome Laurel.

(Applause.)

MS. HOOVER: So most of the work that I'm talking about here and that was contained in the document we sent was Laurel's work, and that's going to be the majority of this agenda item.

The other piece is a very minor, kind of administrative item almost on getting the Panel's input on how we're looking at the possible revision of the listing of PAHs as designated and priority chemicals and get your thoughts on that.

So actually the first thing I want to say before we get started is that this is not a designated item. That this is a pre-screen. And just to remind the Panel,

Gail presented an idea that we had about getting your feedback on before we create a designated document that we would first bring it to the Panel and get your thoughts on whether it's worth doing a designated document. So Gail presented that work in March, and then a refinement of that in July. And now this is our first real implementation more formally, where we did a document using that framework that Gail developed, and that the Panel helped us refine.

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MS. HOOVER: So why screen BPA substitutes and related compounds?

Well, first of all, there's been public and Panel interest in these substitutes. Bisphenol A is a priority chemical for biomonitoring. And many manufacturers are already considering or already using alternatives for BPA. So the emerging alternatives are very likely to increase in use. And the Panel has given us real clear direction about trying to stay ahead of that curve and looking at emerging chemicals of possible concern.

These chemicals are used in consumer products, and there's indications of toxicity. And I'll be talking in more detail about some of what we found.

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MS. HOOVER: So before I get into the meat of it.

We actually started the screen just looking at BPF, BPAF, and BPS. And Laurel quickly uncovered that there are many, many more BPA functional substitutes and structurally related compounds. We also came across the work that U.S. EPA's Design for the Environment is doing.

They're looking at a large set of functional alternatives to BPA that are known or expected to be used as developers in thermal paper. So what we decided to do, and the reason we're calling this a preliminary screen, is that instead of going in more depth on a few chemicals related to BPA or possible substitutes for BPA, we decided instead to do a much broader preliminary screen of the large number of substitutes and related compounds that we've identified so far.

So that little intro, I'll start talking about the preliminary screen.

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MS. HOOVER: So what is this preliminary screen?

What we've done is we're providing you a very brief summary of information located so far on the 23 substances that we've identified as known or expected substitutes or compounds that are structurally related.

Now, why did we make such a long title?

One of the reasons is that some of these chemicals are actually already being used and have been

used, and they're not necessarily specific substitutes for BPA, but we still thought they were interesting because of their structural similarity.

So here it just gives you an idea of what we covered. We were trying to look at information. Again, we used the basic structure that Gail developed on the screening, but we also used the Panel's direction to be flexible, depending on what chemicals we were looking at. So here we looked at chemical identity and structure, use and production, whether they've been detected in consumer products or biological or environmental samples, some physical and chemical properties, predicted bioaccumulation and persistence, and just a very approximate extent of toxicity data and types of endpoints.

So I really need to emphasize that we did not do a comprehensive literature search. We relied on the information that was publicly available and easily accessible to us. So that's why we're calling it preliminary. And actually in this talk, I'm not going to go into depth in a lot of the content. I'm just going to give you a flavor of what we found.

And really, the aim of our discussion with the Panel today is not a decision item, but just input on possible next steps, if any, that the Program should

consider regarding these chemicals.

Okay. So just -- I'm going to give you -- there's a lot of structures in the document. I'm going to show you a few.

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MS. HOOVER: So for comparison, here's bisphenol A. Here's bisphenol A diglycidyl ether, bisphenol AF. You'll see the similarities to the structure on top here. They're substituted with fluorines on the bridge. Bisphenol F, bisphenol B.

So you can see that these are some of the compounds that are currently in use or being considered as alternatives, in some cases.

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MS. HOOVER: This compound is bisphenol S. This is the 4,4' version of bisphenol S. I'm not giving you the full chemical names. You can refer to the document for that. This is TGSA, d-8, bisphenol S-MAE.

So you can see a pattern is emerging where there's a lot of -- there's similarity here to both bisphenol A, but these are what EPA might -- is categorizing as bisphenol S like compounds.

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MS. HOOVER: And then others related to BPS that have some similarities of structure. Here you can see the

SO_2 bridge. This is a polymer. And then Pergafast 201 has the SO_2 bridge. So these are just a sampling of the types chemicals we've been looking at.

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MS. HOOVER: So the other alternatives. Laurel also came across that there's actually some completely different types of alternatives out there.

One is the Tritan copolymer, which is known to be a substitute for bisphenol A, and is actually increasing in sales quite dramatically. This shows the Tritan monomers.

And then EcoCare is another substitute. So the Tritan copolymer has been used in food and beverage containers as a substitute. It actually has at least 23 different formulations of this combination of monomers for its particular applications. EcoCare has been used as -- is being used as a replacement for protective coatings in reusable water bottles, such as stainless steel or aluminum water bottles, but we don't know the specific composition of EcoCare.

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MS. HOOVER: So what are the major types of uses?

Well, it's going to look pretty familiar to BPA. The uses that -- some of the uses that Laurel came across are protective coatings, for example, inside food and

beverage containers, in the production of plastics, developers in thermal paper, for example the cash register receipts that are ubiquitous.

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MS. HOOVER: Here's a little bit of information on production volume. So we've included here BPA for comparison, which is in 2006, was still greater than a billion pounds.

One of the Tritan monomers is also greater than a billion pounds. Another Tritan monomer is between 100 and 500 million pounds. Then there's a few that are still high production volume, greater than a million pounds. Some less than 500,000. And then for many of them, we did not locate production volume.

So here I'm just highlighting which -- so again, we did not -- we really definitely did not do a comprehensive literature search on biomonitoring studies. But those that we came across have detected BADGE, BPAF, BPB, and PHBB, which is benzyl paraben.

In terms of detections in consumer products, again from the survey that we've done so far, here's some of the compounds that were found.

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MS. HOOVER: So Laurel did the big job of running the PBT Profiler on all of these chemicals. And the PBT

Profiler gives you predicted information on bioaccumulation and half lives in various media, and this summarizes the results. PBT Profiler also compares the results to U.S. EPA criteria. And the numbers that are in orange, in this case, indicate persistence. There weren't any orange values for bioaccumulation -- or bioconcentration factor, which is BCF.

The red under the half-lives section indicates very persistent. And then you see a couple of bioconcentration factors that are red, which indicates very bioaccumulative. And this is all predicted based on U.S. EPA criteria.

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MS. HOOVER: In terms of toxicity, in the preliminary screen, what Laurel found was that many of these have limited or no toxicity data. She did locate a number of literature studies and some of the endpoints that we were looking at so far were in vivo, for example, the uterotrophic assay, which is a measure of estrogenicity.

And various in vitro assays for endocrine disrupting activity. There were also some genotoxicity information.

I also wanted to add kind of an interesting side note at this recent SOT meeting. There was research that

is fairly new research on the Tritan and Tritan monomers showing lack of estrogenic and lack of antiandrogenic potential. So those posters were at SOT.

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MS. HOOVER: Again, preliminary screen. You shouldn't really see this as a comparison or an alternatives assessment, in any way, but we're just giving you a flavor that a number of them did have evidence of endocrine disrupting activity in vitro. A few of them had evidence in vivo based on the uterotrophic assay.

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MS. HOOVER: And I did really want to highlight the U.S. EPA's work. So they're doing a major assessment of functional alternatives for BPA in thermal paper. And they're looking at human and environmental health profiles, structure activity modeling, and they also are looking at proprietary information.

And the reason that they can do that is they've actually formed a partnership between, you know, government as U.S. EPA, a number of manufacturers, retailers, NGOs, and stakeholders. And they're trying to work together to assess the alternatives that might be replacing BPA in thermal paper.

And their draft report is actually due out fairly soon, late March or possibly early April, so we can

provide you an update on their findings in the July meeting.

So that's pretty much covering the content of the preliminary screen. If you looked at the document, you know there's more information in the document as well. But like I said, I'm -- the point of this item isn't really to get into the details, but get your feedback on what to do next.

And I also wanted to invite, you know, anyone in the public, any interested parties that if there's -- they have other information, comments on what we've done so far, or additional information that we may have missed, we'd be very happy to receive that.

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MS. HOOVER: So now let's turn to what our questions are for you today. So we're really interested to hear about what next steps, if any, we should take for these compounds. Options include some additional screening. And here I want to particularly thank Dr. Solomon for doing a lot of my work this morning. When we were looking at these compounds, it really struck me for this case, in particular, of how critical it is to do some laboratory screening and not just library research.

And so we're very interested in this idea of looking at possible pilot screening of urine and/or blood

samples from volunteers using some of the techniques that were talked about this morning. This would be, of course, dependent on the ability of the Program to do this, given resources, and we'd also have to find funding for it, and it would not be CDC funding.

And again, there's definitely room for more library research. We could expand the preliminary screen as well or instead of doing laboratory research.

It's also -- you know, even though it's a preliminary screen, you can certainly recommend, well, you know, "We think you should go ahead with a potential designated document". You could consider a subset of these chemicals, perhaps defined by chemical structure or use, or selected individual chemicals, if there's ones that particularly strike you.

So with that, I'll turn the mic over to the chair.

CHAIRPERSON LUDERER: Thank you, Sara, and Laurel for putting together this document. Very informative and it's nice to see this table that was presented conceptually actually being used.

Do we have any questions, first, kind of clarifying questions from the Panel before we go to public comments. And then as always, we have discussion time again for the Panel at the end.

No.

We do have some public comments that came in by email, and I can read those. Do we have any in-person public comments?

So we'll do our in-person comment first. And this is Nancy Buermeyer from the Breast Cancer Fund.

MS. BUERMEYER: Great. Thank you very much, and thanks to staff for that presentation.

I just, on behalf of the Breast Cancer Fund, want to encourage the Panel and the Program to do everything you possibly can to look at these chemicals. We've played a leadership role in trying to educate the public about BPA, the concerns we have about BPA. We've worked not only on baby bottles and sippy cups, but we're working on a market campaign now on cans. And part of the market campaign demand is not just that companies take BPA out, but they tell us what they're putting in.

Recently, Campbell's announced that they were going to phase BPA out, which is a huge victory on our part, but it's only a piece of the puzzle if we don't know what else they're using and what the impact of that use is, in terms of the impact of those chemicals.

So I don't have the scientific answers, but I can tell you from an advocate's perspective and a public perspective, we continually get questions about what else

are they using and what does that mean?

So to the extent that you have resources and ability to move this particular project forward, we would strongly urge you to do so.

Thanks.

CHAIRPERSON LUDERER: Thank you very much for that comment.

I'm now going to read a comment that came in by email. And this is from -- submitted by Davis Baltz of Commonweal.

He says, "My comment is in support of the proposal to screen some bisphenol A substitutes and structurally related compounds as possible candidates for future consideration as potential designated chemicals by Biomonitoring California.

"California has already signaled that BPA is a chemical of concern by passing legislation last year that was signed by Governor Brown eliminating BPA in baby bottles bottle and sippy cups.

"The evidence linking endocrine disrupting chemicals with health effects continues to grow. Just this week, a comprehensive study published by the Laura Vandenberg and 11 colleagues in the journal Endocrine Reviews. The study conducted

over three years reviewed hundreds of studies that examined low dose effects of endocrine disruptors on people and animals. BPA was one of the chemicals examined in great detail. The scientists representing some of the most respected researchers in the field, used striking language to describe some of their findings:

"There is overwhelming evidence that hormone-acting chemicals have effects at low levels, and that these effects are often completely different than effects at high levels."

Number 2, "Associations have been demonstrated between low levels of hormone-altering compounds with infertility and other reproductive problems, cardiovascular disease, neurodevelopmental effects, obesity, abnormal bone health, and cancer."

Three, "Effects are found across the population from fetuses to aging adults."

Four, "The overall cost to society is enormous."

And Five, "Fundamental changes in chemical testing are needed to protect human health.

"Biomonitoring data will be critical for the

State to assess the degree of exposure Californians experience to these and other compounds, so that strategies can be devised that protect public health. Taking initial steps to screen compounds that are structurally related to BPA or are used as substitutes is both prudent and will distinguish California's biomonitoring program from other efforts.

"Thank you for the chance to comment."

And we thank him for the comment.

Do we -- now, since we have no additional comments from the public, we have time for Panel discussion and recommendations.

Dr. McKone.

PANEL MEMBER McKONE: I was looking like I have a question. I don't know if this is a question that I should have asked early. I always get these things backwards. But in the tox screen, I noticed the list in vivo and in vitro, but there was no in silico. I mean there are -- I mean, this is a screen that is not yet -- we're not trying to demonstrate hazard for policy, but is there any thought of the legitimacy of running -- of the EPA software that does structure activity rankings of chemicals? The Canadians have programs. Are those far enough along?

I mean, it's just one more piece of information. We know they're not terribly reliable, but they're getting better with these sorts of things. ToxCast.

MS. HOOVER: Yeah. I mean, I'm not sure, Laurel, if you want to add to that. But I guess we didn't really focus strongly on structure activity, because it seemed so apparent to us, you know, that there was structure activity concerns for these. So that was a little bit of the flexibility.

So actually Laurel focused quite a bit on literature and seeing what was already out there. And we felt that the kind of structural activity concerns were implied just by laying out the structures. However, we certainly could run more. That was the PBT Profiler we ran, which is predictive based on structure.

And, I mean, if you can -- you know, as you pointed out, they're not necessarily reliable. If you have particular tools in mind that you would recommend, we'd be happy to look at that. We did check if anything was in the ToxCast program, and I don't think there's any alternatives included in ToxCast at this point.

We also had a number of discussions with DfE. We were lucky enough to consult with Cal Baier-Anderson, who's one of the leads on the DfE project. And they've done a lot of that work, and that's going to be coming out

at the end of this month. So we'll be, you know, updating you on that from there. That's a subset of what -- well, I think it's -- we pretty much covered almost all the ones that they looked at, and then we did a few more. So they'll be presenting their results of all that type of screening that they did.

CHAIRPERSON LUDERER: Dr. Alexeeff.

OEHHA ACTING DIRECTOR ALEXEEFF: Just to add on to what Sara said. We're in the process of, let's say, developing that particular capability in general in OEHHA. And so once we -- once -- we thought we'd have it by now, but it didn't quite work out, but we will have it soon, because we'll be using it in considering for our looking at green chemistry type of issues and such. So I think once we get that up and running, we'll be able to find more information like that as well.

CHAIRPERSON LUDERER: Dr. Solomon.

PANEL MEMBER SOLOMON: Thank you for this document and for doing this preliminary screen. I think this is -- this represents a really excellent first step, and it's very helpful.

It also is a little bit overwhelming. There's a lot of chemicals here. You know, it might sort of be tempting, as a Panel, to say, yeah, you know, dig in and give us lengthy documents on all of these. But, you know,

recognizing the limitations of staff time and resources, I think it is incumbent on us to try to prioritize among these a bit. And it's a little difficult to see how to do that.

I think, in my view, I see two ways that are kind of tempting to prioritize. One is to sort of toss this over -- this ball over to the laboratory and challenge the lab to do some non-targeted screening on some of the samples that already exist, and see if we can help find a grant to do that. I think there are, for example, private foundations that might be interested in funding something like that, and see what pops up, and then move forward on those.

I think the other possible approach is there are three main categories of uses here, thermal paper, food can linings, and hard plastics. And of those three, the last one is the one that has the most sort of immediate California resonance, because of the fact that in California we just recently banned BPA from baby bottles and sippy cups as mentioned by one of the commenters.

And so in keeping with our, you know, previous practice as a Panel, we obviously are always wanting to stay vigilant about what's coming in as replacements for chemicals that have been subject to public policy decisions in California, which makes it sort of tempting

to focus on the hard plastic uses, which would bring us, I think, to the Tritan copolymer, to the very mysterious chemical maybe, I guess, that -- the EcoCare. Though I guess that's a liner, not really -- yes, sorry.

And, you know, there maybe some -- is a little hard for me to tell, but maybe some of these others also are being used in hard plastics.

Uh-oh. I don't have my glasses on.

And so, you know, to sort of challenge -- and I guess that's sort of a question. Are there others other than the Tritan copolymer that jumped out as being used in hard plastics and potential replacements in baby bottles? And if so, those might be ones that we would want to focus on sooner rather than later.

CHAIRPERSON LUDERER: Sara Hoover.

MS. HOOVER: Yeah. I think that you're -- I did think about California relevance, so I'm glad you raised that. I did want to say that you're right that it's hard to prioritize, and that, in fact, even trying to do something like -- I suggested, for example, by use, but what we discovered, for example, was because DfE did this project on replacements in thermal paper, we had a huge list of replacements in thermal paper. But they haven't done a project like that for replacements in plastics. So we're quite certain that we'd have a huge list that we may

not even be aware of. And we also can't say for sure that we've really gotten a comprehensive handle on what the uses are.

So you'll see in the table, we'll say that it's used in thermal paper, and that's because we know from DfE that they've identified known or expected alternatives.

And actually, one of the cautions even there is that they're not necessarily getting information on all the alternatives that are even in use right now. So just a note. I think it's a great idea, but it's potentially difficult to get the information to make that cut.

CHAIRPERSON LUDERER: Dr. Solomon.

PANEL MEMBER SOLOMON: One other question. Did you have any luck squeezing any information out of the FDA? I've spoken with folks at FDA who -- you know, actually the guy who was in charge of the office that evaluates food can liners. And he said that he's inundated with requests, and that his staff can't keep up with all of these new food can lining substances that they're asking for approval on.

I don't know the degree to which FDA would provide that information, but I think -- I mean, it's not EPA that's doing this, both for the hard plastics -- again, these are all food contact substances, so they all lie within FDA. And so it would, you know, be important

to see what information we could get from them.

MS. HOOVER: Yeah. No, we didn't talk to FDA, so that's an excellent suggestion. And if you have a particular contact, we can follow up with them.

CHAIRPERSON LUDERER: Actually, I had a related question. You meant -- whether there's any information on use in California on any of these chemicals, whether we know whether they're more highly used here than in other places, because that's been another kind of criterion that the Panel has used in the past.

MS. HOOVER: The short answer is no. You know, that's part of what we -- I was -- have done some work in the Green Chemistry Initiative as Mike Wilson has. And that's one of the things that we'd really like to know is how things are used in California, and we don't have that information. I don't know if, Mike, if you had anything to add about that particular question, but...

PANEL MEMBER WILSON: Well, yeah. Only that -- I mean, these are -- this is I think an extraordinary document that you've put together here. And, of course, it's exasperating and possibly thoroughly predictable with the direction we've been going, you know, phasing out BPA, and now we have this whole new crop of multi-dimensional Whack-a-mole, you know, substances.

And, I guess -- I mean, that's what I've been

trying to think through is, is there something that this can -- is there someway that this can inform the State's Green Chemistry Initiative, in that it's a perfect illustration of the need for the State of California to have a process for managing this scenario, and preventing this kind of -- the proliferation of these substitutes for which we have no information from outside of what we can get from the public databases, and, in fact, would probably be flagged for authorization in the European Union, because of their persistence and bioaccumulation potential.

You know, it's a very disturbing outcome. And I don't -- I'm not quite sure what the intersection is with the Green Chemistry Initiative, and maybe it falls outside the purview of the Panel. But this, I guess -- what comes to mind here is similar to some of the work that OEHHA has done on reporting findings similar to this, I mean, around -- some of the work that you've done around occupational exposure limits and the Prop 65 list and so forth that were influential.

I think that it would be interesting to capture this information, and in a way that could be a use to interested parties. And I'm not exactly sure where it would go, except for the fact that these -- the facts sort of speak for themselves.

MS. HOOVER: Yeah. I did want to mention that our program, the Biomonitoring Program, recently had a couple of meetings with DTSC Green Chemistry staff. And I specifically told them about this screen and the kind of work we do in this program on emerging chemicals, both in the pre-screen and in the designated documents, and they were very interested, and very excited to find ways to work together. So that was partly -- that intersection was partly motivated -- you know, this interesting choice of BPA related compounds.

CHAIRPERSON LUDERER: Any other comments from the Panel right now?

I just was thinking, as Dr. Solomon and the other Panel members were talking about other possible ways that one could narrow down this list. And, you know, one thought, of course, would be to look at the work that you've already been doing looking at bioaccumulation factors and the chronic fish value, and the half-lives and choose only those that were flagged using that screen. Unfortunately, when you look at that table, it doesn't winnow it down very much at all.

Another possibility would be something that I think you also mentioned in this idea of chemicals with certain structures. Maybe those that are related to bisphenol A and focusing on those initially. But again,

they're still a large list.

MS. HOOVER: Yeah. I just wanted to add to the discussion that Tom had and that George brought up. We actually did definitely intend to do a lot more work on structure activity. Somebody was supposed to join OEHHA that had something like more than 10 years of experience working in EPA on that, and then it didn't happen. But I do think that that is an area that we haven't explored, which is looking more carefully at particular structures that might be of more concern.

And I know that Laurel identified some papers in the literature that look at exactly that. We didn't go into that in the preliminary screen, but we are aware of that research and that's one avenue that we could pursue more in a further screen, in terms of the library side of the screening.

CHAIRPERSON LUDERER: Dr. Solomon.

PANEL MEMBER SOLOMON: Out of this long list of chemicals, there are five, maybe six, that have both some in vivo evidence of endocrine disrupting activity, and some evidence of -- you know, indicative of human exposure. Those include BADGE, bisphenol AF, bisphenol B, bisphenol F, as in Frank, and 4,4-bisphenol S, and possibly PHBB. It looks like the response in the in vivo study is sort of weak, but that might also fit in this

category.

And so, you know, one option would be to move forward with those five or six, since we think that there might be some data there. But that -- you know, those have somewhat disparate structures, and it's sort of a little tough given -- you know, it's a little tough to justify why not include very closely related paths. But on the other hand, we might want to start somewhere. And so if we did want to move forward, you know, one option would be to do that.

I actually would propose that we do several of these -- you know, move several things forward at once. You know, that we, as a Panel, encourage the Program to seek out additional resources to do some non-targeted screening for these BPA alternative chemicals in a, you know, small pilot study, because I think that that will be useful no matter what.

And then, at the same time, I would encourage the staff to contact the FDA and try to do for the food contact uses what you've kind of done here for the thermal paper uses, because it may be sort of a different list. And I think -- I mean, at least personally, I'm much more interested in the food contact chemicals than the thermal paper chemicals, though I think they're all interesting, and important, I think. If we can get more info from FDA,

that would be really helpful for the Panel. And so that would be just additional research, sort of, preliminary research.

And so then the final piece of what I propose, you know, might be, you know, whether we want to move forward with a few selected chemicals on this list for potential designation in the interim, because, you know, the other two pieces that I just suggested, the laboratory piece and that gathering data from FDA wouldn't actually move the ball forward in terms of designating anything yet. And if we wanted to look at some potential -- you know, possibly designating some chemicals at the next meeting, we might want to identify, you know, a small subset, maybe including those five or the Tritan copolymer, which we do know is used in hard plastics, and very widely used, as something to move forward within the interim.

CHAIRPERSON LUDERER: Any responses or other comments from other Panel members?

Are the Panel members in agreement with the recommendations that Dr. Solomon just made? Any disagreement with those recommendations? I think the -- those are excellent recommendations. Although, the third one still would require that we come up with a list of chemicals, which so far we haven't really had any kind

of a consensus emerge on how we would choose those.

I mean, the suggestion of going forward initially with the ones that have some evidence of the estrogenicity in the uterotrophic assay, which is the in vivo estrogenicity assay would be, I think, a reasonable approach. It's a relatively more manageable subset of these chemicals.

On the other hand, you know, the in vitro screens, which I think, is it correct, that they were done on a larger number of chemicals? It's not that the in vivo, in vitro screens were done on the same numbers of chemicals and they didn't all come up in the in vivo?

MS. HOOVER: We think you're asking if the blank cells mean that they did them and it was negative. No, the blank cells mean we didn't find information.

CHAIRPERSON LUDERER: That's what I thought.

So, I mean, I think maybe I would be in favor of keeping the things a bit more broad, at this point. And maybe those for which there's either in vitro or in vivo data suggesting that there may be concern for toxicity. Any other additional comments, agreement, disagreements?

PANEL MEMBER WILSON: Could you say that again, Chair? Restate that.

CHAIRPERSON LUDERER: So Dr. Solomon's third suggestion was that the -- that maybe as far as chemicals

to move forward on, in terms materials of doing additional library research, and maybe developing a designated document - correct me if I'm not paraphrasing what you said correctly - was to use those that had come up positive in the in vivo estrogenicity studies, which is the uterotrophic assay. And I was suggesting also adding those for which there was some in vitro data. There's quite a few where there's in vitro data, evidence of endocrine disrupting activity, quite a few of them were PAR, CAR interacting chemicals. So that would be just -- I was suggesting broadening it a bit to include those. Any other thoughts?

PANEL MEMBER WILSON: I guess the one question, of course, is that the ones that aren't designated as having in vivo data is that simply because those studies haven't been done? That's probably right.

What do you think we should do, Sara?

(Laughter.)

MS. HOOVER: Well, I guess -- I mean, that's partly why I'm more excited about the idea of doing some lab screening, partly because, you know, we're facing the same issue that we always face of, okay, we're going to look under the lamp post. These are the ones that have been studied, so these are the ones that we're going to move forward.

I don't feel any confidence that, you know, we can exclude others, at this point. So, I mean, maybe we could take a dual approach of doing some of the additional investigation of structures to see the ones that haven't been tested, you know, is there the likelihood if they were tested, is there information to suggest that they would be active, based on a structural analysis. We could do that rather than just leaving them off. And we could pair that work with trying to pursue funding to actually look at what's in people's samples.

So I would tend to take that approach rather than -- and I understand what Dr. Solomon is saying about not being able to move forward, but I really -- I feel, in this case particularly, and just given the green chemistry angle that we want to not just write another document about information that's there, but try to think a little bit more broadly in this case, and take a slightly different tactic than we have before.

That would be my suggestion as the next step, and that we could report back to you on, you know, how successful we think we're going to be about pilot screening, and we could report back to you about, okay, we did some more structural analysis and actually these look like they're going to be more active. And then we would have -- like I said, this was kind of a preliminary

screen, so we are asking you for input, early, early input about what to do next.

But I think that's probably the angle that I would suggest rather than moving to a designated document at this point. I don't know if -- and Laurel says she agrees.

PANEL MEMBER WILSON: Can I ask a clarifying question then, Sara. So you're suggesting a screening approach. Does that mean that we -- that the laboratory would be running a screen on existing samples for this whole pallet of substances?

MS. HOOVER: No. And that's something we'd -- you know, we'd have to work out. I think there's -- you know, there's a couple different approaches that can be taken. One approach that Myrto was talking about is calling around, finding out what people are looking at, what people have successfully found, what reference standards there are. That's one approach.

Jianwen was talking about another approach that maybe use to a qualitative identification. I think we should -- that's what -- when we say investigate possible pilot screening, that's the kind of work we'd have to do is figure out what is feasible and what looks possible. There's also an issue about, you know, depending on the consent for the samples. We can't necessarily run it, you

know, on all sample -- existing samples. So we'd have to look at that issue.

But certainly, I think there'd be some archive samples, and then we have the possibility of doing screening and volunteers as well. So that we'd have to look at, you know, how to make that happen. But I think that that's definitely worth looking at.

CHAIRPERSON LUDERER: Dr. Culver.

MS. HOOVER: Mic.

PANEL MEMBER CULVER: I'd like a little clarification on what you mean by screening in volunteers.

MS. HOOVER: Well, for example, this is something that Dr. Petreas has already done. She has IRB approval for convenient samples. So I was one of her volunteers, for example, when she was testing sample tubes. She's operating under, you know, full regular IRB approval, full consenting, return of results and so forth. So I don't know, Rupa, do you want -- can you say anything more about how you address volunteers that I haven't already covered or have I covered it?

DR. DAS: I think Sara has covered what we're referring to. I just want to mention that that study that Sara is referring to is one of the ones that's described in the initial results return packet.

MS. HOOVER: The pilot. Yeah, the ECL pilot.

DR. DAS: Yes, I don't remember the exact terminology that's used to refer to it, but it is described in the results return packet.

MS. HOOVER: Dr. Culver, can you speak into the mic.

PANEL MEMBER CULVER: Can you describe it just very briefly again.

DR. DAS: I'll describe what I can. Dr. Petreas is the one who would be able to describe it better, but she --

Okay. Michael Lipsett would like to describe it.

DR. LIPSETT: Hi. Michael Lipsett.

At the outset of the Biomonitoring Program, we wanted to be able to test some of the laboratory methods initially. And we got -- Myrto and I initially had written up a protocol for the State IRB to be able to recruit people just to be able to get the kinds of samples that we're talking about right now.

It was initially to test methods for different kinds of -- well, for the different kinds of chemicals we were going to be looking at initially, but that the approval that we got from the IRB was broad enough to encompass the kinds of screening that we're talking about here. So additional samples could be obtained from volunteers to look -- and if we have a -- I understand

actually that our lab may have a TOF even to be able to do this kind of non-targeted screening.

PANEL MEMBER CULVER: Did that include chemicals for which you have almost no toxicological information?

DR. LIPSETT: It's a pretty -- I don't have the protocol here with me, but it was written to be broad enough to encompass a variety of different situations that would occur in the development of the program. Now, I think the principal limitation on it though, at the outset, was it was limited to 100 people. And I don't think we're anywhere close to that in that -- in the numbers that have participated so far.

PANEL MEMBER CULVER: The IRB allows you to give an untested chemical to a person?

DR. LIPSETT: No, no, no, no.

MS. HOOVER: No, No.

DR. LIPSETT: No. No. It's to test the -- I'm sorry. It was initially designed to test analytical methods for looking at different kinds of chemicals in people. It was not to administer chemical -- it was not to do -- I see what you're -- I see where the confusion is.

We would not be administering these chemicals to people. This would be obtaining samples, like urine or blood samples, and then examining them in a non-targeted

way, because we don't have -- necessarily have the methods for these kinds of things developed at this point.

PANEL MEMBER CULVER: So how is the screening done? I'm sorry I'm so dense.

DR. LIPSETT: Okay. My understanding -- I was not here for the discussion this morning, but you can do non-targeted screening using a Time of Flight spectrometer. And we are scheduled to get one of those in DTSC lab under the CDC funding, but I -- and Dr. She could tell us. I think that our laboratory actually -- not his, but within the CDPH laboratory there is a TOF available, if I'm not mistaken.

MS. HOOVER: I think also, Dr. Culver, you probably missed this excellent presentation that Dr. Gerona gave on non-targeted screening at one of our meetings. I believe it was in July, if I'm not mistaken. So I can provide you with that, which gives a lot of technical detail on exactly how the method is done.

And, Jianwen if, you want to say something.

DR. SHE: Under this -- yeah, this case -- I think this is still called a targeted screening, because this -- we already have the chemical structure in our hand. We know which one we're looking for. So that's a lot of full spectrum of untargeted screening.

We targeted on this group of the bisphenol A. We

even do not know the quantity of how much they're there, but we tried to look for, if they are there. We do not look for the quantity of information. So this still belong to a little targeted screening.

So, for example, we know bisphenol F. We know the molecular weight. We put the molecular weight inside the instrument. We know the fragment packings. We put the fragment adult ion there. We try to confirm with it. So I tried to clarify this is a targeted screen, instead of bigger, broader wide untargeted screening.

So, by the way, we do not need a TOF kind of instrument. The TOF machine is tremendous -- mean to follow untargeted screening.

CHAIRPERSON LUDERER: Dr. Solomon.

PANEL MEMBER SOLOMON: Just a quick addition. If this laboratory purchase goes forward, which I hope it will, it would be important to do the due diligence with the FDA early on, because if there are other chemicals that the laboratory should be looking for, we would want to know their molecular weights as well. And so these would be these food contact substances alternatives. And so -- I guess my -- my concern is that it could take awhile to do this, because there's no funding available yet. You know, writing a proposal, getting the funding in place, doing the analytics, et cetera, could be a, you

know, a year before we have anything really to look at.

And so it makes me a little anxious to have chemicals that are, you know, very -- you know, that have evidence of endocrine disruption and evidence of human exposure and some significant likelihood that their use is increasing, that we're not -- you know, that aren't -- that we're just sort of holding off on in our pipeline, until we get these results. And so that's sort of why I was trying to find a way to move a few chemicals forward.

To my mind, that doesn't mean that -- you know, if we look at a small number of chemicals from this list and made a decision on whether or not to designate those, we could still subsequently go back relatively easily and broaden those designations, I would think, to a class, once we have information -- you know, a little bit more information to go on.

MS. HOOVER: Yeah. I definitely didn't mean to imply that we wanted to sort of postpone, but I was trying to -- you know, looking at multi-pronged approach. So I think that -- my only hesitation was in trying to pick from this list now, and saying, yes, let's move these forward for designation. That I personally would -- because that's what we wanted to emphasize, this isn't exhaustive. We haven't looked at everything. We're not a hundred percent sure we found everything. So to base a

decision of let's look at these, I'm just a little bit uncomfortable with that.

However, we can definitely do more work and give you an update, you know, a brief update, on what we found, and then we could -- so we could keep that process moving forward too, along with the lab screening. I agree with you that it's a very interesting exciting process, but there's a lot of things we have to look at in order to actually make that happen, the lab screening, so we can keep the other side moving forward at the same time.

CHAIRPERSON LUDERER: Did you have a comment, Dr. Wilson.

PANEL MEMBER WILSON: I think that makes sense. And I guess I would also -- I keep coming back to this thought that what you've identified here or what you've presented us with is evidence of -- that's pertinent to a structural problem with public policy decision making in California. And that's -- it's -- this is very interesting and pertinent information in that context. And so I guess at the risk of putting you on the spot, my question is, is this information -- can this information be made available to the public or can it be packaged in a form, in that you've done the great majority of the work here, as an interim finding or a report to the Secretary of CalEPA for example?

MS. HOOVER: So this is public, first of all. So it's posted on our website, so the information is public. It's definitely there and this is a public process. So that's the first thing.

In terms of repackaging it, you know, I think that that's definitely an option. I might ask George or Lauren to comment on that idea about a repackaging for that purpose.

(Laughter.)

PANEL MEMBER WILSON: Any takers?

DR. ZEISE: It's something for consideration. I'd be happy to -- I mean, we'd be happy to consider it.

MS. HOOVER: Lauren says we'd be happy to consider that. I want to also note though that what I already said, which is we have made -- for example, I brought up the screen with Debbie Rafael of DTSC. You know, we certainly could brief the Secretary of CalEPA on these findings. You know, those kinds of things are options without moving forward necessarily to repackaging the information.

DR. ZEISE: I was just going to bring up the same thing that, you know, basically we do collaborate with the other programs in CalEPA. We do collaborate with the Green Chemistry Program. So I don't know, George, if you want to add anything further.

OEHHA ACTING DIRECTOR ALEXEEFF: No.

(Laughter.)

CHAIRPERSON LUDERER: Dr. Solomon.

PANEL MEMBER SOLOMON: My suggestion, I think this isn't quite there -- quite to the point yet where we would want to present it more broadly because of the fact that I have a sneaky feeling that a whole lot of chemicals are actually missing here because of the FDA uses. But if you're able to get the information on some of the food contact uses, something like this could be actually, I think, very useful as a journal article.

And I would encourage you to strongly consider writing it up as such, just to discuss the process of assessing alternatives. And, you know, step number one is to try to figure out what -- you know, what chemicals are coming on the market. And you can discuss the fact that some of these are proprietary and there isn't even chemical structure information. Then, you know, others we have the names of the chemicals, and some sense of the uses, but it's impossible to get, you know, use quantities. And for others, there's, you know, no toxicity data or no exposure data. And, you know, really just sort of go through the whole process of what California did in an effort to evaluate this for the Biomonitoring Program. And I think a paper like that

would be extremely helpful.

CHAIRPERSON LUDERER: Dr. Alexeeff.

OEHHA ACTING DIRECTOR ALEXEEFF: Sorry, Gina, that's -- this is George Alexeeff. That's what I was trying to think through in my mind about structuring it for more discussion in the scientific community, some of these issues that are raised from here. And I wanted to see of going back and meeting with staff and talking about how we would do that. But your suggestion is a good one to kind of think that through in that kind of a structure. And I think we should look at the information here and see how we can continue this discussion in the scientific community, because I think it raises a number of interesting points.

CHAIRPERSON LUDERER: Dr. Zeise.

DR. ZEISE: I guess the final thing is that from a toxicological point of view, of course, there's a lot of interesting BPA substitutes. There's a lot of researchers that are beginning to look at these, input, and there is some look through screens. The extent to which these particular compounds have been looked at, we have done some preliminary work, but we haven't sort of scoured the universe for people that are interested in these kinds of compounds.

We were at a SOT. There were people -- the

Society of Toxicology. There were some people at the Society of Toxicology - this was meeting over this past week - that have actively looked at some of the -- some compounds that are BPA replacements. And so another piece of that is to actually further follow up with them.

CHAIRPERSON LUDERER: Dr. Solomon.

PANEL MEMBER SOLOMON: For a paper, it actually would be kind of helpful to focus on what's in the published literature, which I think will not be -- I mean, a lot of the things that are -- you know, that these researchers are currently looking into doing exploratory studies on won't be published yet, and therefore wouldn't be widely accessible to the public.

And so I think that it's important to in a -- you know, if you're going to write this up as a paper, focus on what actually is publicly available, which will only -- which will not be very much for most of these chemicals.

DR. ZEISE: Yeah. And I guess one of the things I was thinking about were the high throughput screens. There is more and more information being made public through EPA's work on their Tox21 and ToxCast project. And there's great interest in BPA, because it lit up so many different pieces on the estrogen disruption screens. And you look at what they call their tox pies.

So there is real interest in BPA-like compounds

as well. And I just don't know the extent to which they've begun to work on that. And NTP is also interested in addition to EPA. So it could be that those high throughput data might be available. I don't know.

CHAIRPERSON LUDERER: Dr. Wilson.

PANEL MEMBER WILSON: Thank you. I just -- I think Dr. Solomon's idea is also -- I mean, is a great idea. And I was actually going to make the same comment that for other actors across the U.S. who are contemplating BPA phaseouts or other substances phased out individually and so forth within -- you know, we have 18 individual States taking actions on chemicals policies of different kinds, and this is sort of the first indication of what happens in the wake of some of those decisions.

And so, you know, publishing it in the literature is a great -- I think would be a great contribution. And doing so, I think you know as Dr. Solomon has said, with information that's available publicly that, you know, a reasonably -- with reasonable due diligence could be obtained by a State EPA and so forth would be a really nice contribution.

CHAIRPERSON LUDERER: Okay. So we need to move on to the end of the presentation. We've gotten ideas from Panel members, and I think we've addressed the questions that you had.

MS. HOOVER: Yeah. Thank you so much for all of the really great input. We will look it over and move forward and brief you in the future on our progress.

So I just want to end the item with this. We've talked about this in the past, and we were going to bring it back to you. And we've thought about it quite a bit. And this relates to working on revising the listing of PAHs as designated and priority chemicals.

And just as a little background, the PAHs that are currently designated are based on CDC. The Panel did move a small number, three hydroxy-PAHs, forward as priority chemicals. And that discussion and decision was essentially based on what the predicted lab capability was at the time.

The lab now has capability for many more PAHs and aren't necessarily measuring the same ones that they had predicted. So we recognized awhile ago that we should revisit PAHs. So the proposal that we are bringing to you today is that the Program -- in terms of designation, I'll explain a little bit more why this would be a good way to go, that we are proposing that the Program would just develop a very simple one pager, basically, to support Panel consideration of PAHs as a class for designation.

And the advantage of that is that it basically gives flexibility to the Program to look at PAHs for

various purposes. For example, there's some desire from the Panel to eventually look into potential markers for diesel. So rather than continually bringing you back PAHs that might be of interest for particular purposes, we could just get the whole class on as designated chemicals, and then we could later consider -- you know, from that, you could either just recommend the full class as priority or you could direct us to look at a particular subset.

But essentially because of the interest in PAHs and the importance the Panel has put on it and the lab capability that's developing, we thought this would be a simpler approach, rather than spending a lot of Program resources on developing multiple documents or more in-depth documents. So this is the -- just an idea we wanted to get your thoughts on before we move forward with something like that.

CHAIRPERSON LUDERER: Any comments from Panel members on that proposal?

Dr. McKone.

PANEL MEMBER McKONE: It makes a lot of sense. I think -- I mean, I recall from our discussions that we were thinking of PAHs as a class, but realized that we couldn't make the recommendation because of the lack of capabilities, so it probably is consistent. I'll have to look back, but I do remember this question of whether we

want to pick them out or do them as a class, but I think we tend to think of them as a class.

CHAIRPERSON LUDERER: Dr. Solomon.

PANEL MEMBER SOLOMON: Well, would this include nitro-PAHs?

MS. HOOVER: We could -- yeah, I mean, I guess we could define the class how we would -- what would make sense. So we certainly could. We could define it that way. We could define it a certain way. I do know that part of the discussion actually was a discussion with Dr. Luderer or Dr. Solomon about, you know, being careful about which PAHs that you actually ultimately focus on for priority purposes.

So what I'm proposing now is to just simplify matters, because it becomes a little difficult when we have a subset, because our designated list starts off with a lot of these as a subset of chemicals based on the CDC's lab capability. I mean, that's where the designated list comes from. So the CDC's capability changes and shifts. They drop some. They might add some more. Those we can automatically deal with.

But in terms of the Program's development and potentially striking out into new areas, it would be simpler to have the class designated. It would give the Program that flexibility, if the Panel has that level of

interest. Otherwise, we have to just continue to change our designated list based on CDC, and then, you know, bring you additional ones as documents, first for designation and later for priority. So we're just trying to streamline the process of moving forward on other PAHs. And that's just one idea.

CHAIRPERSON LUDERER: Dr. Solomon.

PANEL MEMBER SOLOMON: I'm honestly not sure that a one-pager would be enough, but I think I would -- I mean, I would support the staff bringing back to us a proposal to look at PAH's as a group as designated chemicals. I think it might -- we might need a little more than a page of information to go on, just because it is a complex class, and has been broken down in various different ways by different researchers. And some PAHs have toxicity weighting factors and others don't. And so we should, you know, have the information in front of us about which ones, you know, are incorporated, you know, in the usually weighting schemes for carcinogenicity or non-cancer toxicity, and which ones are being biomonitored versus not by any entity, and sort of looking at the different ways that PAHs break down, so that we can at least have some sense of what we're getting into and recommending. But I don't think it needs to be a huge document, but I'd like a little more than just sort of,

like, yes to all PAHs, because it's very complicated.

MS. HOOVER: Yeah. I mean, maybe I'm overstating one-pager, but basically simplified. You know, a simplified designated document. I don't think that it's worth it to put a lot of Program resources into developing the kind of designated document we might do on emerging chemicals. You know, the toxicity is well known, and --

PANEL MEMBER SOLOMON: Right. You don't have to re-explain to us why PAHs are bad.

MS. HOOVER: Exactly. Exactly. That's my point is, you know, can we move forward in a simple way to try to clean up this listing problem and give the Program flexibility. That's the idea.

CHAIRPERSON LUDERER: Yeah. I think a tabular format summarizing a lot of the information that's already out there would, you know, probably be a way that would be preferable than going chemical by chemical and coming up with a designate -- I mean, you know, that could take a very long time.

Do other Panel members have any comments on this item?

So there seems to be agreement among the Panel members to move forward with the idea for an abbreviated document to consider PAHs as a class.

We did -- we do have actually, I think, a public

comment that came in by email about -- that's related to the PAHs, so I will read that now. This is from Matthew Gribble, at I believe it's the Johns Hopkins School of Public Health.

And he says, "Dear, Scientific Guidance Panel, I would like to recommend the synthetic musk fragrances as an exposure of interest for monitoring in at least a sub-sample of the California population, in particular the common musk Galaxolide, which is a High Production Volume chemical found in many consumer products.

"Polycyclic musks, such as Galaxolide, bear many structural similarities to PAHs and are likely common exposures in the population, but little or no systematically sampled survey data are yet available, so there is not a clear picture of the true prevalence of these chemicals in human tissues.

"In convenience samples from around the world, these chemicals generally show up in greater than 90 percent of the sampled participants, and these chemicals appear in multiple matrices, including blood, adipose tissue, breast milk, and even umbilical cord blood. Toxicological information is sparse, but

there is some evidence suggesting possible endocrine disrupting and chemosensitizing, (such as xenobiotic metabolism and transport-impacting) behavior for these chemicals.

"Therefore, it would be very beneficial to begin understanding how common these chemicals actually are in the general population and whether large scale epidemiological studies would be a useful investment for the public health community.

"I'm attaching a partial (not systematic) reference list on these chemicals if this email has raised any interest in learning about and potentially measuring this probably very interesting exposure. I think synthetic musks would be a very valuable thing to consider including in the California Environmental Contaminant Biomonitoring Program.

"Thank you."

So that's -- any comment or reactions to that from Panel members?

Dr. Solomon.

PANEL MEMBER SOLOMON: Yeah. Well, I actually have one other thought about the PAHs, which is, you know, the other question about PAHs is, is there a molecular

weight cutoff that we might want to think about? Like the -- you know, sort of get down into the asphaltenes and these extremely big heavy compounds that are probably not all that well absorbed, and, you know, a certain point we might want to consider a cutoff that these, you know, chemicals are just too big and maybe not. But I would just encourage -- that would be a question that I would have in the, you know, listing of PAHs as a class, whether we want to look at that. And so I'd like to see something on that in the document.

But on the nitro-musks and musk xylenes, I think those are -- that's a very, very interesting group of chemicals. And I actually don't know why it hasn't come up before.

MS. HOOVER: It's on our radar. It's part of what we have on our list of things to screen definitely. So it has come up, and Gail has done some research on musks already.

PANEL MEMBER SOLOMON: I would be very interested in seeing more.

MS. HOOVER: Yeah. With regard to your comment about the weight cutoff, we can certainly look at that. You know, that also could be a possibility in terms of priority chemicals, you know, just to keep the designation simple and just get it designated and find an appropriate

way to describe the class, you know, on the designated list, and then consider more detailed considerations, you know, in terms of moving things forward as a priority for biomonitoring in California. So that would be one way to handle that.

But we'll certainly consider your comments and, you know, think about how to talk about the class and provide as much information related to that as we can in the abbreviated document.

CHAIRPERSON LUDERER: Okay. Thank you.

I think we need to move on, because we do have an open public comment period here before we wrap up.

And we have received one comment via email. Do we have any people who would like to speak?

Thank you.

All right. We'll take the in-person comment. This is from Trudy Fisher.

MS. FISHER: Hi. I'm always glad when you have the meetings in Oakland, because it means I can come in person and thank you so much, myself, for all the hard good work you're doing, especially today's meeting.

There's just been such a qualitative leap forward. I can't believe it. I feel like we're finally -- it's finally happening. Everything that was mandated is really set in motion and we're seeing results

and so on. So thank you so much.

As someone who worked seven years in a building that had ventilation problems next to an autobody shop where the chemical were being vented out for worker safety and into my building, I was like the household dust, you know, the passive screener. And 20 years later, I still have cognitive problems and other health issues from that. So obviously this project is very dear to my heart.

I just wanted to give specific feedback very quickly on two things. One is Table 3 in the second presentation that Dr. Das made. Just as a member of the public, I actually thought it was -- I thought both the presentations were just wonderful. Table 3 I thought was very readable. The column at the end that talks about detection and so on, just as someone from the public, I had a great response to that. When you see those high figures in 100 percent of the people that we look -- or people, Californians, that we looked at, 95 percent, whatever, we found this chemical.

It seems to me that that's what was mandated with this legislation. I think it's a very effective body of facts. If you want to then break it down, certainly on a website all you do really is you could click on that 100 percent. It could take you to a separate page where there would be an NHANES reference. And as a matter of fact, it

could be as specific as you need it to be for that chemical, because it has a page devoted to itself.

And then even in the print version of that, certain it's just one additional page. So that was just a thought. But I certainly thought to see that listing, especially with those high percentages, was very effective.

The one other very quick thing is that early this -- or earlier this morning, when we were talking about the FOX study, just that in thinking about kind of getting the details to other firemen and so on, so they would have that knowledge, I just would want to say, as somebody who is chemically overreactive and so on, to hope that the people would then possibly buy additional personal protective equipment and so on. My feeling is that personal protective equipment could be part of the problem. You know, you're there. You're wearing supposedly fire retardant fire protective things on your skin. You're breathing it in. It's close. That could also be the source of some of the toxins. So just a thought. But thank you so much really.

CHAIRPERSON LUDERER: Thank you very much for your comment.

I'm going to read the public comment that came in by email as well. This one is from Davis Baltz of

Commonweal.

He says, "I'm sorry I'm not able to join you today in person, and realize that Biomonitoring California's budget is not an agenda item. Nevertheless, I believe it's important to comment on the value of our State's Biomonitoring Program as we hear reports that the Program may face cuts that would make it virtually impossible for the Program to carry out its mission and statutory mandates.

"California has invested important resources in this program since it was created in 2006. The statute laid out an ambitious plan for California to develop biomonitoring capacity that promotes and protects public health by determining levels of human exposure to priority chemicals in our State over time. This in turn would enable Californian to identify vulnerable populations or communities exposed to hire levels of chemicals to assess the effectiveness of current regulations, to indicate priorities for subsequent legislative or regulatory action, and to evaluate the effectiveness of these interventions.

"The dedicated staff of Biomonitoring

California drawn from the Department of Public Health, DTSC, and OEHHA, have done an outstanding job of building this Program, despite chronic underfunding since the Program's beginning. Important laboratory equipment has been acquired, staff have been hired and trained, public outreach has been conscientious. Significant extramural resources have been mobilized, most notably via the five-year MOU with the CDC. One could not ask for more from the people who work daily for this Program.

"Similarly, the Scientific Guidance Panel, which was created to advise the Program, has been a model science advisory panel. It has provided thoughtful and strategic input in an atmosphere of profession integrity and civility.

"At the time the legislation that created Biomonitoring California was enacted, polling data showed an overwhelming majority of Californian voters, 83 percent, supported the creation of the Program. Californians want to know about toxic chemicals in their bodies.

"As a public interest stakeholder who has followed this Program since its inception, I can assure you that community groups and NGOs across

the State continue to support our biomonitoring program. They have recognized the Program has developed more slowly than originally envisioned because funding has never been sufficiently to accomplish its mandates, but they are eager to utilize Program findings as they now start to come on line, and they are full of ideas for additional studies that would shed light on Californian's unique chemical exposure patterns.

"As you have heard today in staff presentations, data are being generated that are enormously useful contributions to public health. It would be extremely short-sighted to sacrifice this Program as the investments in its development are now producing returns.

"Furthermore, ongoing CDC support would be threatened, essentially throwing away funds that have already been raised. Let's remember that Biomonitoring California's budget was initially in the general fund. When its budget was transferred to DTSC's TCSA account some two years later, there was trepidation that the Program's future would be more vulnerable. DTSC is an important partner in Biomonitoring California, but the Program is a collaboration of three

agencies, and it is not solely a DTSC program, by any means. A return to a stable funding mechanism is needed and this will require a common recognition that biomonitoring is necessary in California.

"Biomonitoring provides us with essential data that will enable California to stretch scarce public health resources, ultimately saving the State millions of dollars in health care costs and environmental remediation. We cannot effectively understand human diseases and environmental health risks until we collect and establish the human exposure database that a scientifically based biomonitoring program can provide.

"Thank you for the chance to comment."

And thank you very much for the comment. I think the Panel agrees with much of that, most of it, all of it.

PANEL MEMBER SOLOMON: All of it.

(Laughter.)

CHAIRPERSON LUDERER: Any other comments from Panel members?

Okay. Well, that is the -- Dr. Das, did you have a comment?

DR. DAS: Thank you, Dr. Luderer. I have a

follow up from one of my presentations this morning. One of the Panel members asked about the response rate or refusal rate for BEST, the Kaiser representative sample, and I have some information. I think we'll present more detailed information at a future Panel meeting.

But I did want to get back to you, because I said I would. We have data back from three counties where the recruitment has, and enrollment has been completed, because we have quotas for each county, and that's Sacramento, San Joaquin, and Fresno counties.

And the enrollment rate varies, as I said, by county between 12 percent and 24 percent of everyone who was invited to participate. We are still recruiting enough participants -- well, we're sending -- we continue to recruit until we have the quota for each county. So we don't stop. If we get people who choose not to participate or who don't respond, we continue to send out invitations until we get the number we want. But the enrollment rate is -- varies between 12 and 24 percent. And it's a little complex. It's difficult to explain without visually representing it, but I just wanted to present that information.

It is a -- if you just look at the numbers, it's a relatively labor intensive process to keep recruiting people until you get the number desired, but because

we're -- we have Kaiser and the ability to stratify and choose potential participants electronically, it saves us a lot of effort.

CHAIRPERSON LUDERER: Thank you very much for that clarification and that additional information. I would think that with the Kaiser database one would also have the ability to be able to at least do some sort of an analysis to see whether those people who didn't choose to participate differed in any kind of -- you know, some sort of systematic way from those who did that may be worth considering, if it's possible.

DR. DAS: Certainly, all the data is electronic in the Kaiser system, so that's information we can get. And what I'm not describing in detail is there are certain people who decline to participate and others who did not respond, and still others who are eventually not chosen because we filled our quota, so it's a little more complex than just a refusal rate.

CHAIRPERSON LUDERER: Thank you.

Okay. All right. So then I would like to announce before we close that the next Scientific Guidance Panel meeting will be held in Sacramento, and the date for that will be July 26th, 2012. And with that, I'd like to adjourn the meeting. Thank you again for coming and for your participation, for the great discussions and

presentations that we had today.

Thank you.

(Applause.)

(Thereupon the California Environmental Contaminant Biomonitoring Program, Scientific Guidance Panel meeting adjourned at 4:54 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 26th day of March, 2012.

JAMES F. PETERS, CSR, RPR
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