CHEMICAL SELECTION WORKSHOP

STATE OF CALIFORNIA

OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT

ENVIRONMENTAL CONTAMINANT BIOMONITORING PROGRAM

SCIENTIFIC GUIDANCE PANEL

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APPEARANCES

PANEL MEMBERS

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Dr. Asa Bradman

Dr. B. Dwight Culver

Dr. Marion Kavanaugh-Lynch

Dr. Ulricke Luderer

Dr. Thomas McKone

Dr. Julia Quint

Dr. Gina Solomon

Dr. Michael P. Wilson

OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT

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Mr. Allan Hirsch, Chief Deputy Director

Dr. George Alexeeff, Deputy Director, Scientific Affairs

Ms. Carol Monahan-Cummings, Chief Counsel

Mr. David Berger, Cancer Toxicology and Epidemiology Section

Dr. Gail Krowech, Cancer Toxicology & Epidemiology Section

Dr. Martha Sandy, Chief, Cancer Toxicology and Epidemiology Section

Dr. Charles Vidair, Pesticide & Food Toxicology Section

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

APPEARANCES CONTINUED

DEPARTMENT OF PUBLIC HEALTH

Dr. Frank Barley, Supervisor, Research Scientist

Dr. Paramjit Behniwal, Research Scientist

Dr. Peter Flessel, Chief, Environmental Health Laboratory Branch

Dr. Robert Haas, Chief, Food & Drug Laboratory Branch

Dr. Rick Kreutzer, Acting Chief, Environmental & Occupational Disease Control Division

Dr. Sharon Lee, Staff Toxicologist

Dr. Michael Lipsett, Chief, Exposure Assessment Section

Dr. Robert Ramage, Research Scientist

Dr. Jianwen She, Chief, Biochemistry Section

Ms. Robbie Welling, Reseach Scientist

DEPARTMENT OF TOXIC SUBSTANCES CONTROL

Dr. Myrto Petreas, Chief, Environmental Chemistry Branch

ALSO PRESENT

Dr. Kerstin Becker, Federal Environmental Agency

Dr. Henry Clark, West County Toxics Coalition

Mr. Doug Haines, Health Canada

Dr. Marike Kolossa-Gehring, Federal Environmental Agency

Dr. John Osterloh, Centers for Disease Control and Prevention

Ms. LaDonna Williams, People for Children's Health and Environmental Justice

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PROCEEDINGS

REPRODUCTIVE AND CANCER HAZARD ASSESSMENT BRANCH

CHIEF ZEISE: I'd like to welcome everyone to our Workshop on the California Environmental Contaminant Biomonitoring Program.

And to start and welcome you, I'd like to introduce Dr. Joan Denton, who's the Director of the Office of Environmental Health Hazard Assessment.

Joan.

DIRECTOR DENTON: I'm just going a take a few moments here to welcome everyone. We have some invited speakers from the CDC, from Canada and Germany, that we'll be hearing from later. We have members of our Science Guidance Panel and our staff. And the individuals from the public who have come, we appreciate your attendance.

Just to remind everyone about why we're having this workshop. It's actually the result of a suggestion made at the Panel's first, and happens to be only, meeting that we held last summer, our Science Guidance Panel on Biomonitoring. And at that meeting we discussed a process for selecting chemicals for biomonitoring, which will be the subject of tomorrow's Science Guidance Panel. And it was suggested -- the Panel suggested at that meeting that we bring in, that we invite other biomonitoring programs to kind of lay out for us how they selected or how they

went about selecting their chemicals for biomonitoring. And as a result, we have invited key individuals from the United States Federal CDC, the German and the Canadian programs, to tell us about their programs and some specifics about how they select chemicals for biomonitoring. This will be very important for us because, as you know, this is an exciting new program for California. We obviously have budget constraints; and so the more advice that we can get about the selection of chemicals, the better that we'll be.

So tomorrow we'll have our Science Guidance Panel meeting. And we will not only have the opportunity to talk about today's meeting but also talk about activities from December until now. And so we invite you all as well to attend tomorrow's meeting.

So, again, the speakers, we appreciate you coming to California; we appreciate the public members for being here; we appreciate the Panel members for taking time to be here.

And I just want to mention the very hard working staff on behalf of Cal EPA, the Department of Public Health, OEHHA, and DTSC. It takes a lot of people to manage to put on these meetings and to manage the program. So I'm just going to take a minute to particularly thank Michael and Lauren and David, Frank, Peter, Amy, Farla,

Diana, Sandy, Gail, Robbie, Myrto, Maria, Jocelyn, and -- Peter, Frank.

So I wanted to mention everyone. Thank you so much.

(Applause.)

DIRECTOR DENTON: So with that, I'm going to turn it over to Lauren.

REPRODUCTIVE AND CANCER HAZARD ASSESSMENT BRANCH CHIEF ZEISE: Thanks, Joan.

So as Joan pointed out at the last meeting -- at the one and only meeting of the Panel in December, we were asked to hold a workshop to hear from the other programs, and hence today's workshop. Tomorrow we will have the full meeting of the Panel.

And today we're going to hear from speakers from the CDC, the German and Canadian programs. They'll tell us about their programs. And we've asked, as particularly with respect to chemical selection, they tell us about the processes used to select chemicals, the criteria they used, the chemicals they've selected. But we've also asked them give us some background on their program, including program goals, resources, scope issues such as population study, and then implications for regulation of toxic chemicals.

So we've organized the agenda for today by having

the three speakers in the morning present us on their -- give us presentations on their program. And after each speaker we'll have five minutes of clarifying questions. Then we'll have time for a discussion after the speakers -- after the three speakers come up, we'll have a more general brief discussion and then we'll break for lunch. And we'll come back in the afternoon, and Michael Lipsett will moderate a more extensive discussion in the afternoon for a couple hours.

And then the Panel and speakers are invited to tour the DTSC laboratory. So that will happen later on. I think we'll be meeting downstairs at 3:30 to do that.

So, let's see, logistics: The Panel we're sent briefing books. This particular meeting is covered in -- the workshop is covered under Tab 1. We have packets for the presenters in the audience. And in those you'll see the slides for today's meeting, the lists of chemicals that the other programs are biomonitoring for.

So, with regard to emergency exits, I was going to give directions. But I think the best thing to do is just follow the signs. It's pretty complicated. So look up and follow the signs, the green signs, the exit signs.

For lunch, you're on your own. It's a beautiful day. There's the City Center. And we can direct you to that. Once you go down the escalator, you turn right and

go about a block down and then just -- it's across the street to your left. Lots of places to eat there, and then some other restaurants and we've got a sheet of paper indicating where those are.

So I think before diving into presentations -- first, I saw Rick Kreutzer come in who's the Acting Division Director at California Department of Public Health. And, Rick, would you like to just say a few words of welcome as well?

CDPH ENVIRONMENTAL & OCCUPATIONAL DISEASE CONTROL DIVISION ACTING CHIEF KREUTZER: Okay. I'd be very happy to.

Good morning to everybody. And I would simply say that I'm very, very happy to be here with you all.

It just seems that --

REPRODUCTIVE AND CANCER HAZARD ASSESSMENT BRANCH CHIEF ZEISE: Rick, we're recording this, so you need to use the microphone.

There's one right there, if you'd like, or here.

CDPH ENVIRONMENTAL & OCCUPATIONAL DISEASE CONTROL DIVISION ACTING CHIEF KREUTZER: And all of that for a grand recording of a welcome.

But it is a pleasure to be here with all of you. I'm extremely excited about being involved in public health at a time when there are so many important issues

that are emerging. And this biomonitoring program is an opportunity to develop a resource that all of us can share - communities, researchers, public health practitioners - together, and at a time when we're thinking about trying to change chemicals policy, trying to track the developments, trends and patterns on very big broad public health issues. Having a resource like biomonitoring to fit into that picture is an extremely exciting possibility.

So it's wonderful to be here with all of you to try to craft the best instrument that we can.

So thank you, and I look forward to spending today and perhaps even tomorrow with you.

Bye.

REPRODUCTIVE AND CANCER HAZARD ASSESSMENT BRANCH CHIEF ZEISE: Thanks, Rick.

So maybe before diving into the presentations, if we could just maybe go around the room and just introduce ourselves, maybe just giving your name and your affiliation. I guess I'd like to start with the Scientific Guidance Panel. Maybe, Ulricke, if you could just start that.

It looks like we'll have to pass the mic, Diana.

PANEL MEMBER LUDERER: I'm Ulricke Luderer. I'm in the Division of Occupational Environmental Medicine at

the University Of California, Irvine. And I do research in toxicology.

PANEL MEMBER BRADMAN: Asa Bradman with the Center for Childrens' Environmental Health Research at UC Berkeley. And I work on exposure assessment issues.

PANEL MEMBER SOLOMON: I'm Gina Solomon. I'm currently on sabbatical from the Natural Resources Defense Council.

It's gone again.

And I'm at UCSF in the Division of Occupational and Environmental Medicine.

PANEL MEMBER WILSON: Mike Wilson.

(Laughter.)

PANEL MEMBER WILSON: Come in Houston. There we go. Mike Wilson at the Center for Occupational and Environmental Health at UC Berkeley.

CHAIRPERSON MORENO: Good morning. Ed Moreno. I'm the Health Officer for Fresno County and the Director of the Department of Public Health in Fresno County.

PANEL MEMBER McKONE: Tom McKone, University of California Berkeley, School of Public Health and also the Lawrence Berkeley Natural Laboratory.

PANEL MEMBER CULVER: Dwight Culver, University of California Irvine, School of Medicine, in the Department of Epidemiology, although I'm not really an

epidemiologist.

(Laughter.)

PANEL MEMBER McKONE: My interests are in the field of occupational and environmental medicine.

REPRODUCTIVE AND CANCER HAZARD ASSESSMENT BRANCH CHIEF ZEISE: Okay. Thank you.

Maybe if we could then turn to the speakers.

MR. HAINES: Good morning. My name is Doug Haines. I'm with Health Canada in its Safe Environments Programme.

DR. BECKER: Good morning. My name is Kerstin Becker. I'm from the Federal Environment Agency in Germany. And I'm involved in the German Environmental Survey, what we are going to present.

DR. KOLOSSA-GEHRING: Good morning. My name is Marike Kolossa. And I also work for the Federal Environment Agency in Berlin in Germany, wherein our main part of the Department is in Dessau.

DR. OSTERLOH: Good morning. John Osterloh. I'm with the CDC at the National Center for Environmental Health, Division of Laboratory Sciences.

REPRODUCTIVE AND CANCER HAZARD ASSESSMENT BRANCH CHIEF ZEISE: Okay. Thank you.

And I see that Panel Members Julia Quint and Marion Kavanaugh-Lynch have just joined us. So if you

could just introduce yourself by giving your name and affiliation.

PANEL MEMBER QUINT: Hi. I'm Julia Quint. I'm retired from the California Department of Public Health, Hazard Evaluation System and Information Service. Sorry I'm late.

PANEL MEMBER KAVANAUGH-LYNCH: I'm Marion Kavanaugh-Lynch, Director of the California Breast Cancer Research Program. And sorry I'm late.

REPRODUCTIVE AND CANCER HAZARD ASSESSMENT BRANCH CHIEF ZEISE: Okay. Thanks for coming.

Maybe if we could then just, maybe starting with Carol, if you want to just --

CHIEF COUNSEL MONAHAN-CUMMINGS: Good morning. I'm Carol Monahan-Cummings, Chief Counsel for OEHHA.

DIRECTOR DENTON: For those who weren't here when I just said welcome, my name is Joan Denton. I'm the Director of OEHHA.

DEPUTY DIRECTOR ALEXEEFF: Good morning. I'm George Alexeeff, Deputy Director for OEHHA.

CDPH ENVIRONMENTAL & OCCUPATIONAL DISEASE CONTROL DIVISION ACTING CHIEF KREUTZER: Rick Kreutzer -- hello again -- Division of Environmental and Occupational Disease Control, California Department of Public Health.

CDPH ENVIRONMENTAL HEALTH LABORATORY BRANCH CHIEF

FLESSEL: Good morning. My name is Peter Flessel. I'm the Chief of the Environmental Health Laboratory in the California Department of Public Health.

CDPH BIOCHEMISTRY SECTION CHIEF SHE: Good morning. I am Jianwen She, and I'm Chief of Biochemists Section Worker for Dr. Peter Flessel.

DTSC ENVIRONMENTAL CHEMISTRY BRANCH CHIEF PETREAS: Myrto Petreas. I'm with the other laboratory, environmental chemical laboratory of Department of Toxic Substances Control.

CDPH EXPOSURE ASSESSMENT SECTION CHIEF LIPSETT:

Michael Lipsett. I'm Chief of the Exposure Assessment Section in the California Department of Public Health.

REPRODUCTIVE AND CANCER HAZARD ASSESSMENT BRANCH CHIEF ZEISE: Okay. Thank you.

I guess we have time to finish going around the room. So maybe -- it's going to be hard with the mics.

Would it be okay if people just stand and loudly proclaim their name and their affiliation?

THE COURT REPORTER: Sure.

CDPH STAFF TOXICOLOGIST LEE: Sharon Lee. I'm with the California Department of Public Health. I serve as a toxicologist.

CDPH RESEARCH SCIENTIST WELLING: I'm Robbie

Welling. I'm with the California Department of Public Health in the Biomonitoring Program.

DR. KROWECH: I'm Gail Krowech. I'm with OEHHA.

CDPH RESEARCH SCIENTIST SUPERVISOR BARLEY: Frank Barley, staff in the laboratory of Environmental Health.

CDPH RESEARCH SCIENTIST BEHNIWAL: Paramjit Behniwal with the Environmental Health Laboratory.

CDPH RESEARCH SCIENTIST RAMAGE: Good morning. My name is Bob Ramage. I work with these two and Peter in general.

REPRODUCTIVE AND CANCER HAZARD ASSESSMENT BRANCH CHIEF ZEISE: Bob, do you want to...

CDPH CHEMISTRY SECTION CHIEF HAAS: Good morning. Bob Haas, Chemistry Section Chief, Food & Drug Laboratory Branch of the California Department of Public Health.

DR. VIDAIR: Charlie Vidair, OEHHA.

MR. BALTZ: Davis Baltz with Commonweal.

MS. LUTSKY: Marta Lutsky. I'm a biomonitoring intern with the California Department of Public Health.

MR. GONZAGA: Phil Gonzaga with the Environmental Investigations Branch, Biomonitoring Program.

REPRODUCTIVE AND CANCER HAZARD ASSESSMENT BRANCH CHIEF ZEISE: Would you like to say hello?

MR. VOETSCH: Hello. I'm just a visitor.

(Laughter.)

REPRODUCTIVE AND CANCER HAZARD ASSESSMENT BRANCH CHIEF ZEISE: Okay, fine. Welcome.

MR. LADD: Larry Ladd, Community Advisor for Aerojet Superfund site issues. And this is Greg Voetsch, who was the poster child for the report in the Wall Street Journal.

MR. BERMAN: Howard Berman from Dutko Worldwide.

MS. FISHER: Trudy Fisher --

REPRODUCTIVE AND CANCER HAZARD ASSESSMENT BRANCH CHIEF ZEISE: Could you -- I'm sorry, because of the transcriber, if you wouldn't mind just speaking pretty loudly.

MS. FISHER: Trudy Fisher. I became chemically sensitive in the early nineties when autobody paint chemicals were coming into the building where I worked. And I'm currently writing a book on environmental illness.

REPRODUCTIVE AND CANCER HAZARD ASSESSMENT BRANCH CHIEF ZEISE: Thank you.

MR. GARISH: Bob Garish, CalOSHA.

MS. BERTRAND: Hi. Michonne Bertrand from the Minnesota Department of Health Biomonitoring Program.

MS. HOOVER: Sarah Hoover, OEHHA.

MS. CAMPLEMAN: Sharon Campleman.

MR. WONG: I'm Pat Wong from Air Resources Board.

MR. BUTLER: Bill Butler, Environmental Risk Analysis.

MS. TSAI: Feng Tsai with OEHHA.

MR. HOROWITZ: Mike Horowitz, CalOSHA.

MS. HELGESON: Kirsten Helgeson with OEHHA.

MS. CLANCY: Heather Clancy, just a recent grad from UC Berkeley.

MR. FERRELL: Jeff Ferrell with CalOSHA.

OEHHA CANCER TOXICOLOGY AND EPIDEMIOLOGY SECTION

CHIEF SANDY: Martha Sandy at OEHHA.

MR. MILLER: Mark Miller with OEHHA.

MS. HANSEN: Linnea Hansen, U.S. EPA.

MS. GENTZ: Robin Gentz with the Clorox Company.

MS. LU: Ye Lu with CDPH.

MS. ZHANG: Li Zhan. I'm with CDPH.

REPRODUCTIVE AND CANCER HAZARD ASSESSMENT BRANCH

CHIEF ZEISE: Okay. Did we get everyone?

Oh, sorry. Sandy McNeel.

CDPH RESEARCH SCIENTIST McNEEL: Sandy McNeel, California Department of Public Health, Environmental Health Investigations Branch.

CDPH RESEARCH SCIENTIST LEE: Diana Lee, also with the same branch.

REPRODUCTIVE AND CANCER HAZARD ASSESSMENT BRANCH

CHIEF ZEISE: And David Berger, who can help you with any

of your needs, he's not in the room now. So if you have -- you need something, please contact David. But you'll see him coming in the door and roving around. So he's pretty identifiable.

So welcome, everyone.

And, you know, this is kind of a deep room. And people way back in the back, if you have difficulty hearing, if you could just please fill free to speak up. Okay? Or if you have difficulty seeing. Can everyone see the slides?

Okay, great. We will be dimming the lights.

Okay. So I guess now we'll go into our presentations. And our first presentation, we're pleased to have with us John Osterloh of the Centers for Disease Control and Prevention, or the CDC. He's the Chief Medical Officer and Toxicologist in the Division of Laboratory Sciences, and he's been a key advisor to CDC on biomonitoring. He's also identified on CDC's website as the most senior medical toxicologist.

So John has spent a good deal of time in the Bay Area at UCSF as a medical resident, as a professor, and as a director of the toxicology laboratories at CDC -- sorry -- at UCSF.

Welcome John.

(Thereupon an overhead presentation was

Presented as follows.)

DR. OSTERLOH: And I'll pour myself a little water here.

It was about ten years ago that I left the Bay Area and after spending about twenty years here, and now I wonder why I left. The weather's so nice and cool. I left 95 degrees in relatively high humidity in Atlanta. So it's really a blessing to be here.

Also, Larry -- I wanted to say that Larry Needham, who was scheduled to be here today, sends his apologies, but he had his kidney taken out. And I wanted you all to know that he's doing fine, and I'll include a few slides of some of the stuff that he gave me.

I guess we're indicating next slide by pitching to you. So we'll get started.

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DR. OSTERLOH: I'm going to talk a little bit about biomonitoring in general because I'm the first speaker, but also about chemical selection and our National Exposure Report.

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DR. OSTERLOH: Generally for those who of us in public health our mission with regard to environmental chemicals is primarily to detect those chemicals or the exposure to them and the diseases that they cause, assess

the health risks based on scientific evidence, implement interventions, and assure that those interventions are effective.

Next slide.

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DR. OSTERLOH: Biomonitoring, which is the measurement of chemicals in blood and urine, can help meet all these public health goals. And in order to explain that, I'm going to give you a little bit of background on biomonitoring.

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DR. OSTERLOH: So what are the attributes of biomonitoring? It's a more direct indicator of exposure and of internal dose, but not necessarily the dose as we think of it in traditional terms, than traditional estimated intakes.

It has the advantage of being measureable, individualized, not estimated or average like we traditionally do.

It's inclusive of multiple exposure routes. So everything that comes in through skin or through the air or through the gastrointestinal tract, we can measure inside the body.

It also has the advantage when you're considering metrics for health effects that there are fewer sources of

variability between that measurement and the effect or the site of action.

Next slide.

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DR. OSTERLOH: To understand what I mean, we need to go back a little bit to traditional dose estimation processes. Keep in mind that estimating the dose, that dose metric is the foundation of what we do for risk assessment. If there's a dose and there's an effect in animals usually associated with that dose, that's how we predict whether there might be effects in people.

So how have we done this typically in the past? We have to look at things like air levels, water levels, soil/dust levels, food levels. We have to measure all of those. We have to then estimate how fast you breathe, how much water you drink, how much soil or dust goes into your GI tract, how much food you eat; multiply all that out. And then if you look down at the bottom -- I think we have a -- one of these things is a pointer here -- if you look down at the bottom, we then have to figure out how much actually gets absorbed, so these are multiplied by various absorption coefficients.

And then when we consider all of that and human condition, we have to realize that these are all modified by various human related factors. Once we model a dose,

we can then predict effects in people or we can predict the levels in people, if they might predict effects in people.

Next slide.

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DR. OSTERLOH: If we go to the larger concentration -- or dose exposure effect paradigm where we look over here and we have an external exposure, it gets into your blood, it distributes and acts at the target site, you have a target effect, and then you have your observed effect, all of these pathways are modified by various sources of variability.

If we start measuring here, we can avoid all of these sources of variability that are over here in terms of estimating the dose, as I just mentioned in the previous slide, the different sources, routes, amounts, duration, behaviors, et cetera.

If we get over here, we've at least avoided those sources of variability. But we have to deal with all of these other sources of intrinsic variability that occur in the body.

Now, what we're talking about with respect to what's affecting these variabilities is kinetics, dynamics, and homeostatic mechanisms that sometimes hide an effect when there is an effect.

Next slide, please.

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DR. OSTERLOH: What we hope to get to in most biomonitoring is a place where we've gotten to in lead. And of course we've gotten to this place by having a tremendous amount of information that's been developed over the last 100 years really with respect to the effects of lead as they're related to blood lead. And here we're talking about blood lead concentration in a chronic or equilibrated state.

And if you look at this little scaler that I have here on this slide, if we see levels down here, we can predict that certain things are happening and levels in here certain things are happening and levels up here certain things are happening.

Now, generally we divide these things into things we can see or clinical effects. So a person who might walk in with colic or -- or a kid with colic or encephalopathy is likely to have levels that are higher than 80, and we'd be using blood lead to confirm that clinical presentation.

Things we can't see are subclinical, and generally we have to do special tests to see that they're occurring. But they're occurring on a deterministic basis.

And then there are things that we can only predict are occurring on a risk basis down below this line.

So once we have a lot of information, we can use biomonitoring as a metric for the effects that might be occurring in the body.

Next slide, please.

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DR. OSTERLOH: Of course in human condition, we have some complications. Not only do we have these other intrinsic sources of variability; but we have all of these other factors that are extrinsic to the human situation usually and that they're added with time, such as diseases, other drugs, other chemicals that can be coming into the body and having effects, behavior in the environment and nutritional factors. All of this tends to make it harder to have a concentration/effect relationship that we can rely on. Either it moves the curves or it broadens the curves and makes it harder to tell if we know a person's concentration what the effect is going to be.

Next slide.

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DR. OSTERLOH: Well, having that little introductions, what do we do with biomonitoring? Well, I can tell you from our background at CDC what we do with

it, and I've divided it into these categories:

There's epidemiologic investigations, which is a lot of what we do at CDC. And when they involve chemicals, we often use biomonitoring to estimate the prevalence of excess exposure. So if there's some kind of chemical spill and people have symptoms, we wanted to look at those people that have been exposed to the chemical if we found them in time.

Also, when we're trying to define what a case is versus what a control is or what somebody who has been exposed or isn't exposed, it helps with the case definition, because we can define those people that would be studied or followed further by the fact that they have the chemical in their body.

Similarly, in research and risk estimation processes, biomonitoring really helps the exposure assignments. Many times in research we have to say, oh, these people over here who are going to be our expose group versus these people over here are our control group, to say that they were exposed we use things like proximity, they're four miles away, they're one mile away; activity, what they were doing at the time, how much time they were doing that, the duration of those activities. And biomonitoring can really help you at least with respect to exposure assignments for setting up a research

study.

Also, what we're seeing a lot of these days is the validation of external dose estimates. In other words, those traditional estimates that we make in terms of what's getting into the body, we can reverse -- do reverse dosimetry by taking the amount in urine or blood, working backwards and saying, "Okay, this is what the dose was that got into the body," and we can help validate those external dose estimates.

There's also concentration/effect relationships, which I alluded to earlier, that we hope to build in terms of research and benchmarking.

And then the determinants of the concentrations in the body. This is a lot of what we do with NHANES; because there's so many other variables that are collected in large observational surveys, that we can sometimes relate those variables, the common ones such as demographic factors, to the concentrations that are in body.

In terms of health care, biomonitoring has been used for a long time, mostly either in overdose situations, people who are acutely ill, or in occupational exposure situations where sometimes the exposures can be higher.

Generally speaking though, for many of the tests

that we'll be talking about today, they don't have a role in medical applications because we haven't validated them with respect to categorical accuracy. By and large, you also need a concentration/effect relationship established, which for most of all though the chemicals that we actually end up talking about today we have not yet been able to establish in the human situation.

So the last thing that we do also in public health is to describe the public's exposure, to let other people know what people are exposed to.

Can I have the next slide.

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DR. OSTERLOH: What are we trying to do here? Basically we're trying to say who is exposed and to how much. What types of chemicals? Sometimes it's a matter of not just knowing the chemicals that are there, but knowing that one chemical is more important than another chemical.

To be able to monitor time trends. We've been doing this now with lead since the seventies. Lead was one of the first chemicals to be included in national surveys. And we've been watching it decline for many years as a result of public interventions particularly with respect to gas and paint.

Look at prevalence above thresholds basically for

selected subgroups in the population.

Use it in risk assessments, as I've described already in terms of working backwards to get a traditional dose, or use level-to-level kind of comparisons - levels of concentration in the body to levels in animals that are showing effects.

Establish reference values for comparisons to other populations, and to set new research directions.

In other words, if we know what the chemical concentrations are in the body and we know which chemicals there, scientists can then say, "I'm going to study these chemicals because they're important, and these chemicals at these levels because these are the levels that people are actually exposed to."

Next slide.

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DR. OSTERLOH: So our exposure survey is called the National Report on Human Exposure to Environmental Chemicals. And it's an ongoing assessment of chemical exposure in the U.S. population. The measurements are carried out by my division, which is the National Center for Environmental Health. We have 400 people, and about 250 of them are actively involved in measuring many of these chemicals.

The survey itself, for those of you who don't

know, is carried out by the National Center for Health Statistics. They're located up near Washington DC. And they run these mobile exam centers. The National Health and Nutrition Examination Survey runs these MECs, as they call them.

Next slide.

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DR. OSTERLOH: The National Health and Nutrition Examination Survey has been run since 1971, usually in six-year surveys. There have been three six-year surveys up until 1999. Now, it's a continuous survey and they collect about 8,000 people -- or they end up with about 8,000. They target about 10,000. They end up with about 8,000 people every two years. And they go to about 30 different localities about the country in those two years.

I'm not going to spend too much time on NHANES this time around. But the data that's collected includes a very extensive questionnaire, takes a very long time to fill out if you've ever seen it. There are just tons and tons of questions about human health behaviors and people's personal situations. There's a physical exam that includes, depending on different groups: For kids there's hearing tests. For women -- postmenopausal women, there's bone densitometry and things like that. And then there's medical and nutritional laboratory tests. And

they've been collecting blood in the survey for a number of years.

And what we do -- next slide.

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DR. OSTERLOH: That's good.

Back one.

There we go.

What we do is we take some of that blood and we use it to measure the environmental chemicals. And we've been doing this since 1999.

And in the third report where we measured about 148 chemicals, it relates -- it breaks down to be about 350,000 high-quality analyses. So we're representing the entire U.S. population by measuring 2,500 people.

This one-third random subset of the NHANES collected population is still representative because it's a random subset. But the overall NHANES program or design is a probability -- multi-stage probability cluster design that is mainly targeting age, race ethnicity, and sex. So it's representative of those three demographic parameters.

So the descriptive data that we present are geometric means, percentiles and confidence intervals for age, gender, race ethnicity.

The releases that we've had in 2001, 3, 5, and 8 correspond to 27 chemicals the first time around, 116

chemicals the next time around, and 148 chemicals in 2005. And in 2008 we're going to be -- next slide --

--o0o--

DR. OSTERLOH: -- measuring 148 chemicals -- excuse me -- 265 chemicals.

In the last report, the 148, these were the chemical groups that we had. I'll just let you read those And you can find all of this information at our website, WWW dot CDC dot GOV slash exposurereport, one word. And you can pull down any parts of the report or all of the report. The exposure information that's contained in the report is the largest survey of human exposures in the world.

The next report -- the next slide, please --

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DR. OSTERLOH: -- shows the chemicals that we're adding this time around. I'll let you read down those. Some of these are chemicals that we've been working on for a long time.

Some of the information that I've been showing here is actually out - speciated arsenic, polybrominated diphenyls, environmental Phenols, and perfluorinated chemicals. We've already written up papers and published in the scientific literature on these.

One of the things we're hoping to do rather than

wait for successive reports to get out, because we're slowing down trying to get all these chemical out, is to try to publish papers on the individual chemicals that are in the news or new to us and get that information out faster.

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DR. OSTERLOH: I'd like to mention a few limitations. First of all, the presence of a chemical that we find in the blood or the urine does not imply disease. More research is needed. And as I alluded to earlier, we don't have that benchmarking that we talked about with respect to internal dose as being a metric for what's happening in terms of health effects. The report itself is an exposure report. We don't go into health effects other than to summarily review some of the background information. But we're not trying to tie the concentrations to health effects, because we don't have that information.

The other point that I'd like to make is that only aggregate levels, that is, the statistical point estimates, are representative of U.S. population. That may seem like an obvious thing to say to some of you perhaps. Individual levels are not representative, in part because of things that cause individual levels to be

up or down. Generally these are -- these tend to be random kinds of effects that wash out in a large population study and look at your statistical point estimates. So collection timing problems; inter-individual differences such as kinetics, body size, and other factors; and then unique rather than ubiquitous exposure.

The data itself is also not representative of locations, unexamined special groups, special products, seasons of the year. And just to clarify, we don't select people -- or NHANES does not select people with regard to exposure or nonexposure.

Having said that, I'd like to mention that the reports that we've put out over the years have had impacts. We've seen where improved dose estimates and risk assessments have occurred, particularly for things like mercury, with the EPA in terms of their setting their RFD with regard to mercury, working backwards from actual biomonitoring data, not necessarily our data all the time. But other people's data and special studies, they've been using biomonitoring data.

Recently -- a more recent example is perchlorate. Perchlorate's been in the news of course, and people are using now biomonitoring data to look at risk estimates with respect to perchlorate.

It's been done with dioxins also by the EPA, and in the literature for things like PFOA and phthalates.

Targeted research at human levels. We've seen -- since we came out with a lot of the original phthalate biomonitoring data back in 2001, we've seen more research being targeted at levels that occur in humans.

A number of trends have been observed, including those for organochlorine pesticides, particularly lead and cotinine. We're working on a few more right now, because we're getting into the period where now we have three survey periods of data and we can start looking at trends.

We've seen comparisons to other populations with respect to the exposure report values, particularly epi-investigations. The World Trade Center, we measured a lot of firefighters there who had levels of different things like polycyclic aromatic hydrocarbons. They were compared to the exposure report.

Occupational exposures. Regional pesticide exposure studies, including those that are going on in the State of California.

And comparisons to other surveys, including the German Environmental Survey and the New York City NHANES study.

So we're seeing that the exposure report is going to some good use. But how did we get into selecting the

chemicals that we got into? Part of this is maybe not something that you can follow exactly, because we had the benefit of being involved in -- that is, people who preceded me and for the seven years that I've been there -- we had the benefit of working on biomonitoring for a long, long time. I was doing biomonitoring when I was here in California a long time go. And people have been doing biomonitoring, you know, for probably 30 years.

But CDC goes back to investigations of Times Beach, Missouri and dioxins; and more recently, as I mentioned, perchlorate. And a lot of the chemicals we already had methods for and we were applying to populations, so they were smaller groups or research studies. And these were the chemicals that when we began working with NHANES and using the blood that was -- blood and urine that was available were the chemicals that we applied.

Now, I'd like to make sort of a footnote about technology. Technology's a great thing. And as we've moved forward in time, we've been able to measure more chemicals. If you go back to those 30 years ago and with first times our group measured dioxins, we were actually measuring them in lipid. And we're not talking about lipid in your blood. We were measuring it and taking a sample from somebody's abdomen and taking the fat out and

actually trying to measure the dioxins in the fat.

Later, we were able to measure it in about a pint of blood. Okay, so had to take almost one unit of blood out of the body to measure. Now we measure it in six mils of serum. But that is still a lot of blood when it comes down to the kind of volumes that we get out of NHANES.

The other side of technology is that we can measure things that we didn't think we could measure. And once we start looking and calibrating, we can find things and we're able to measure them. One example is we measured 13 metals in the urine by ICP-MS. Now, this has turned out to be a common methodology and a lot of labs are doing it now this way. But when we started, we calibrated on a number of interesting metals. But we also found that there were several other metals there that we could easily measure, such as tungsten and cesium, for which there was virtually no human data on toxic effects and actually very little animal data. But there is prevalent exposure to both of those chemicals, and so we've measured it.

Subsequently we found in certain Epi studies that there have been places where there have been higher exposures to the metal tungsten. And now there's investigation going through the National Toxicology Program to look at tungsten as a potential chemical that

gets into people and understand its toxicity.

So things like technology have not only driven our ability to measure them but to find other chemicals, that in some cases are problems, perhaps in other cases are not problems.

Well, after we got started we set up what we call the nomination, which is probably an over-bureaucratic word for trying to find out what other people were interested in.

And this was a one-time process. We're going to start doing it again in the future, along with a process of trying to ask for delisting of chemicals from the exposure report.

We formed a working group back in 2001. And this advisory group was formed from our panel of external advisory folks to the National Center of Environmental Health. They helped develop the criteria for nomination.

To make a long sorry short -- these are on next slide --

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DR. OSTERLOH: -- and basically were very broad, and boils down to these that are here: The potential for changing or persisting exposure to the U.S. population, seriousness of suspected or known human health effects, proportion of the population likely exposed, a need to

assess the efficacy of public health actions, the existence of an analytical method, and the costs.

So we actually were interested in all of these. But I'll tell you that costs and the existence of an analytical measurement are going to be final dictates in being able to do some of this. Because if you don't have a method, forget it. And if you can't afford it, forget it.

So by and large, the grading was done with respect to toxicology on the first four criteria, and the last two criteria were graded in essence by our division.

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DR. OSTERLOH: So this went through a fully regulated slow federalized process of going out for public comment on the proposed criteria, which we did get a lot of comment and helped shape those final criteria that you saw. The final criteria were then posted in October of 2002 and nominations were solicited. We got nominations for 4,000 -- or 400 chemicals -- excuse me -- and we then sent these chemicals out to a panel of medical toxicologists for scoring their level of interest in these.

Now, people asked me, you know, how much science went into this. Very little science went into this in

reality. Most of it was with respect to their broader perceptions of what chemicals might be of interest to us at CDC when applying those criteria.

The nominations were posted in September 2003. There was no threshold for actually listing a chemical. And there was no obligation for our division to actually enter a chemical to the report. And I again emphasize the interest aspects of this process.

The nominations reflected much of what we already had planned for future reports. And, in fact, the first three reports in 2001, 2003, 2005, which was our last report, had not been influenced by this because of the time lag in terms of getting these things out. In other words, we're measuring stuff for NHANES 2006 and 7 -- 7 and 8 right now as those samples are coming in. So to be determinate of what we measure, we have to get this information at a much earlier time.

We also have to go through a petition process with the National Center for Environmental Health and -- or, excuse me, National Center for Health Statistics to get a chemical onto the NHANES survey.

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DR. OSTERLOH: This is the categories that we had. We broadly put them into five categories. This is

the Group 1 category. And anything outlined in red or underlined in red here is something that we already had planned in the works. And this bigger group here represents mostly the perchlorinated chemicals, many of which are perfluoroctanoic acid, salts or esters, which all boil down to PFOA.

So we were already planning to measure these, along with manganese, mancozeb, dimethoate, and benzoapyrene.

We're working on some of these others as we speak.

One interesting candidate you see down here on the bottom -- these are just in alphabetical order, by the way -- is trans fatty acids. And when you think about a trans fatty acid is these are chemicals, they are introduced into our body. And we're interested in that because we work with several other centers that are interested in chronic disease as well as cardiovascular health effects and -- so we're going to be measuring those.

The assay for these, by the way, is extremely slow. It's quite arduous. And we don't know whether we're going to able to turn around these as fast as some of the other chemicals that we measure.

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PANEL MEMBER SOLOMON: Can I interrupt you with a question?

DR. OSTERLOH: Yeah, sure.

PANEL MEMBER SOLOMON: We saw the diesel exhaust. Was that the last slide? So is that something you're planning to measure? And if so, how?

DR. OSTERLOH: Well, I think the category that was proposed was markers of diesel exhaust. Obviously it can't make all diesel exhaust. And one of the things that we are kind of working on -- we already measure quite a number of polycyclic aromatic hydrocarbon metabolites. And we're trying to find one that's more specific for diesel exhaust. And we've met with several industry representatives on this in terms of what they think about this, and we've gotten some ideas from those folks. We've run through various candidates. The problem is that it turns out nothing's absolutely specific. There's some probably better indicators than others.

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DR. OSTERLOH: So I guess with respect to California and some other places -- we've also been working with the United Kingdom on their starting biomonitoring program -- there are a number of places one can start. One can take lists from other biomonitoring

programs such as ours and start there. But the basis for, you know, your regional interests in biomonitoring I think should be based on what you know about chemicals in your region. Since our exposure report isn't necessarily representative of any particular region, including California, it's good to know what's going on here. And one place to start, as I'm sure many of you are aware, is to look at various existing reports on production use and waste reports. Some of these are national but regionalized, and some of these would be California State mandated reports. Others have to do with ongoing contamination events and existing environmental measurements that go on in the laboratories that we have representatives from here today.

One of the things that I think would be interesting to do is to pair some of the environmental measurements with some of the biomonitoring measurements.

Lastly, knowing what chemicals are in products that are pervasive and are used by a wide part of society.

Surveying the public. I hear California is doing that. I tuned into their website and looked at their web-based survey. That's very nice. I think too it's a good idea to talk at least to industry and advocacy groups. I think both of theme obviously have their interests, but they also have scientists and people who

are very concerned about chemicals, and they can give you great insights.

Lastly, as I was asked this morning about toxicity rankings, is why not start there. And I think in the best of all possible worlds, it might be reasonable to start there. But this is pretty difficult to do as it turns out. You're going to start on one end with a chemical that's most toxic, botchalinum toxin, and you're going to end up with water at the other end of the spectrum, and everything else falls in between.

You're going to have chemicals like trichloroacetyl chloride, which is a very irritating chemical. But nobody uses it. It's used in small amounts in production and laboratories, but it's not widespread exposure. So where do you put that? What do you do with that once you know that something like that is, you know, a respiratory irritant?

What do you do when you want to compare acute chemicals to chronic chemicals? It's easy maybe to get LD50s on a lot of chemicals and rank them in order. But you're usually not considering acute toxicity. You're usually considering chronic toxicity. So how do you scale chronic and acute toxicity?

Well, how do you scale things like reproductive toxicology versus carcinogenic effects? Where do you put

those? If you have one chemical that's 100 milligrams per gilogram toxic and produces a reproductive effect, do you rank it higher than another chemical that's 100 milligrams per kilogram because it produces cancer? I don't know. The problem is in doing this and really trying to come to some order with it.

The best thing to do is to know what chemicals you're going to deal with, what chemicals are out there. Partly doing biomonitoring and small surveys and pilot studies and things like that help you know that. Partly looking at what's known about your environment helps you. And then you can get into -- you know, if you want to prioritize one chemical being more toxic than another, you can start to look at that. But to do it up front I think is a bit difficult and a really large task. And as we know, there are other federal agencies that have been working on such things for a very long time.

So in developing biomonitoring, selecting the chemicals is one thing. And to select chemicals you should know a little bit about the specimen and the matrix that you're going to measure them in. We have a wide variety of matrices that we can use. Generally speaking, we're usually confined to blood and urine for most things except special studies. There are times where you want to know what's in breast milk because -- for instance,

because it's the infant that's being exposed.

Generally speaking, when you talk about the best specimen, you want to know whether the specimen or the chemical in that specimen is going to represent the target organ exposure and/or whether it's a significant fraction of the dose or the body burden.

You also have to keep in mind that the chemical should be stable, it shouldn't break down, it should not have any other interferences. Generally we don't have too much problem with this when using high technology mass spec applications, but it does happen.

Uncontaminated. You don't want other sources either from the subject, from the collection system, or from the laboratory analysis to contaminate the sample.

When you ask what's the best chemical form to measure, you have to think a little more kinetically about whether you're going to measure the parent compound, the metabolite, or perhaps an adduct if the chemical's reactive.

You also want to know whether you're thinking about whether this measurement that you make is representative of present, past, cumulative, or integrated exposures.

Biomarkers can be biomarkers of effect, as I said, when you have the dose -- or the concentration

metric related to the effect, or they can just be biomarkers of exposure, again being most of our chemicals.

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DR. OSTERLOH: This slide is -- if you can see it from the back of the room -- is a hypothetical single exposure to a nonpersistent type chemical, where generally the chemical disappears from the blood in a very short period of time. This is a log scale of time; this is concentration. So the concentration drops off relatively quickly. If you measure that same chemical or its urinary metabolite in the urine, you buy yourself a few days, as the window of opportunity expands and you can measure it for a few days, sometimes a few weeks.

If you have a reactive chemical, it may bind to something like albumin in the blood or hemoglobin; in which case albumin will buy you a couple of weeks, hemoglobin will buy you a couple of months.

But generally speaking, those kinetics, while important, are not the kinetics that we're too concerned with with respect to the kinds of chemicals that we want to biomonitor.

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DR. OSTERLOH: Generally these windows of

opportunity in terms of timing really don't apply so much, because we're really thinking about chemicals to which you're exposed to every day, and your concentration is either accumulating or it's going up and going down and going up and going down. So we have to think about continuous or intermittent exposures. We have to think about the sample matrix, as I said, the chemical form and the half-life.

Perchlorate's a chemical that has a short half-life of about eight hours. You'd think, okay, if you, you know, were too late, you wouldn't measure anything at all, because a lot of it would disappear within a day but we're exposed to it all day long. So you're basically looking at some kind of fluctuating level through the course of the day.

In order to precisely look at those chemicals, particularly with regard to individuals, you need to know something about the toxicodynamic and toxicokinetic relationships.

Now, I'm not going to explain all this because we don't have time. I'm going to give you one example about distributional within dose kinds of equilibrium. A steady state generally -- if I had not been exposed to, say, arsenic, which has a half-life of about two days, it would take me about five half-lifes to get up to some

steady-state level.

Okay. So if I was only interested in me, I should wait about five days after I started taking in my daily dose of arsenic.

Concentration/effect's equilibrium comes back to this benchmarking idea, in that if you want to have a relationship between concentration and effect, you need to have some kind of equilibrium established as I mentioned for blood lead earlier in the talk.

For large population samples, most of these things tend to boil down to be random effects. You can be on the high side, you can be on the low side for some people. But your statistical point estimate will give you an average of the overall exposure.

For individuals or small group comparisons, these kinetic conditions are very important. And generally you should try to standardize your collection times with respect to exposure times.

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DR. OSTERLOH: This is the one example I want to give you. Is that if we're measuring a urine of some concentration and this is the dose interval, let's say, I got up and I had my glass of arsenic-ladened water at the hotel this morning and I don't drink any more all day

long, then my dose goes up, the concentration goes up and comes down within, say, a day's period of time. It might end up at the end of the day a little higher before I take my next dose.

But there's a lot of variability, both intra-subject and within subject. And this variability is contributed to mostly by variability in absorption and variability in distribution. So the best time to actually measure the concentration in the body is over here, not at time 1 or time 2, but at time 3. The reason is that this concentration is proportional to the amount in the body or area under the curve. Its also proportional to effects with greater precision when you actually get that far in looking at effects.

And there's a trade-off. Concentration's lower. If you're working right down by your detection limits for -- as we often do for many of these methods, you're going to be getting lower levels rather than higher levels.

So these things need to be taken into consideration, again mostly when we're talking about doing smaller studies or looking at individuals and comparing individuals.

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DR. OSTERLOH: There's several types of survey sampling that come up with respect to biomonitoring surveys.

One is the convenient sample. This is a good place actually to start if you're just trying to look for whether or not to go ahead. It's sort of like a pilot. It's also a good place to just keep your hands on so that you can look for different types of chemicals if you're trying to find out whether there are exposures that you want to include in a larger survey.

The targeted type of survey, which is sort of my word for a stratified probability cluster, which is what NHANES is, requires information that you need structurally before. And NHANES is based on the U.S. census. So we're targeting the U.S. census with respect to age, race ethnicity, and sex.

A random survey is much more costly to do, because you're going to spend a lot of time making sure that you got a random sample. It requires bigger N as well as compared to targeted survey.

So generally you have these general choices. There are a couple other choices.

Another little strategy that we like and we're starting to use recently is pooling of your samples from a larger survey, because it reduces your analytical costs

and it can improve some of your limits of detection.

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DR. OSTERLOH: As I mentioned for the dioxin-like chemicals, we're taking 6 mils to measure about 27 different chemicals that compose the TEQ or the weighted potency-based level of dioxin. So these can be TCDD-type equivalents on this access.

And what we've done here for 2001 and 2002 is we -- out of the 2,500 samples that we had, we only measured 500 pools. So there was a 5-to-1 kind of pooling. And we were able to look at -- still within various age groups, various ethnic groups and sex, we were able to get the concentrations at a median for the national population. So these medians are representative of the U.S. population. It didn't cost us as much time or energy -- analytical time, and we still got that information.

But what we don't have are percentiles, in other words the distribution of the population, how high they go. And that would also convert into prevalence of higher exposures if you were applying that information.

But this is a unique way to go when you have some information, some chemicals where you want to save on some money.

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DR. OSTERLOH: Our methods are very expensive. They're all high-end reference methods using mass spec technology. They have stable isotope internal standards. A lot of these just for a few milligrams of chemical costs us anywhere between, say, 10,000 and $50,000 just to enter into the assay for calibration purposes.

Rigorous QA and contamination control. We spend a lot of money on that in our laboratory too.

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DR. OSTERLOH: Let's skip this slide.

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DR. OSTERLOH: In terms of interpretation of biomonitoring data, you need to understand the application -- and I've made this point several times -- in terms of population and point estimates versus individual values. You're really using two different processes if you're entertaining research where the process is an inferential one versus a deductive one in epidemiology and medicine.

The identification of unusual exposures. Obviously you need to focus on very well characterized LODs and background levels.

Health effects. You have to have a

concentration/effect relationship. And when they're applied, you need to make sure that you have a comparable situation. This is as simple as comparing men to women in some cases. But many, many times the situations in terms of collecting or the kinetics or other things are just too different to even make the comparisons.

Finally, understanding sources of imprecision and variability. Analytic imprecision usually is very small when you're talking about a big population study. But when you're talking about individual testing, it's very big in many cases.

Intra- and individual subjects types of variability. We talked about this at the very beginning, but you need to be aware of it.

Finally, relational imprecision. If you're talking about a concentration/effect relationship, a dose-to-concentration relationship, those types of things, usually these relational forms of imprecision are very broad and it makes it hard sometimes for us to actually interpolate what one thing is from another.

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DR. OSTERLOH: Finally, with respect to California, I'd like to make one example. You can compare California to national data. People have done that. New

York City compared their data to ours, looking and showing that Asians have much higher exposure to mercury than the national exposure study.

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DR. OSTERLOH: I just wanted to point out, this is an example of our tables from our exposure report. And you can see here that DDE, the metabolite of DDT in the body, is higher in older people than it is in younger people and higher in Mexican-Americans than it is in non-Hispanic whites. And these are the geometric means.

And what I thought California could do -- next slide, and then I'll try to sum up --

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DR. OSTERLOH: -- is that we know that with respect to Mexican-Americans in the national study, this concentration is higher. But could California help resolve why that is so? One thing we know about NHANES is that they sample many of the Mexican-American population from places like California and closer to the border. So there could be some form of sampling bias with respect to the national population of Mexican-Americans.

There could be a factor of immigration in that DDT wasn't removed from use in Mexico until about I think 2001.

And then there's the possibility of worker exposure in terms of higher workers in agriculture.

So could California help us here: I think it might be if they were to look at this organochlorine.

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DR. OSTERLOH: I'm going to skip here.

Let me just mention the first thing.

Oversight and scrutiny. This is very important. I think as California gets into this, please, please, please, always keep all of your constituents aware of what you're doing, be transparent. Make sure that when you talk to somebody, you talk to somebody else and that, you know, you're always letting everybody know what you're doing.

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DR. OSTERLOH: Just to summarize. Keep in mind that biomonitoring may be useful as a dose metric. It can reduce our sources of variability. It may relate to the target site of action better.

Know your limitations. Know if you have a concentration/effect relationship or not. Know whether you're studying individuals or populations.

Finally, biomonitoring surveys we found that are

useful. They can help us with prevalence, trends, reference values, and improving in risk assessment.

I think I've gone over my time, because I've been reminded several times here. So I will stop there. Sorry for running through it very quickly.

Thank you.

(Applause.)

REPRODUCTIVE AND CANCER HAZARD ASSESSMENT BRANCH CHIEF ZEISE: This is terrific. Thank you.

I think we're going to change the agenda a little bit and allow for a little bit more exploration after each talk. And we're going to have plenty of time for discussion across presentations in the afternoon. So we'll have a little more Q and A -- extended Q and A now.

PANEL MEMBER McKONE: I have a question but I don't have a microphone. And it seems that's important.

Thanks. That was very interesting and I think helps us get into the issues in a number of ways.

I wonder if slides -- we've talked about the selection of chemicals and you spent a lot of time talking about the toxicological factors as a screening. And somewhere else you mentioned emissions magnitude. But since this is a measure of exposure, I find it interesting that there's not a lot of discussion about exposure screening. And there's been some work showing what

chemical properties make things more persistent in the indoor environment, in the ambient environment, make them more likely to bio-accumulate through certain pathways.

Is there an effort to sort of begin to use exposure or chemical properties information in some sort of a screening analysis to pick out what chemicals are going to be likely hits? And it would also be very interesting in terms of understanding broad behaviors across the chemical class. I mean to me that's as interesting as making sure you capture, you know, the really toxic substances.

DR. OSTERLOH: Well, I can answer that question in terms of another program. The Agency for Toxic Substances and Disease Research Registry has recently -- well, they've been in computational toxicology for quite a while. And most of that's related to kinetic models within the body. But lately -- they held us a symposium recently, which I attended part of. And some of the folks that came to the meeting were actually talking about that very thing, in terms of trying to predict the types of chemicals that would get in the body. Obviously, many of us are aware of some general principles. You know, a lipid soluble compound might go through the skin, for instance. That type of principle.

And to be more refined about it, some of these

people who have computational expertise are thinking that way. So far it isn't part of our laboratory program, but we're keeping an eye on that.

There are other folks, both in private industry and in academia, who are looking at a similar thing of reversed dosimetry and forward dosimetry in trying to predict what kinds of levels we would see based on external doses.

PANEL MEMBER WILSON: I mean, to pick up on Tom McKone's question and -- I think, you know, the challenge that you've framed here really well is how we nominate chemicals in a way that's both scientifically robust and also efficient and avoid -- you know, avoiding Type 1 and Type 2 errors along the way. And so you noted I think in your talk that the chemicals that were nominated along the way, that actually very little science went into that process. It went out to medical toxicologists. They used their best judgment. And I suspect that was a result of, you know, a real lack of information on the use and exposure and toxicity across the spectrum of substances.

And so one of the things that we're really struggling with in California is what is the most useful information -- if we were to ask producers who are selling product in California for a basic set of information, perhaps as a condition of sale, what that information

should look like, and what's the most useful information without overburdening producers.

And so I guess my question is: As you've gone through this process, what do you see as the most important and useful information the we might consider?

DR. OSTERLOH: Well, I think this perhaps may be -- you know, as far as an agency question to answer might be more along the lines of what EPA might try to answer for you.

Analogous to the earlier question though, there's many of us who work both in the laboratories and out in the field and with samples and different types of chemicals. And we're aware of various physical properties of chemicals that would tell us where they would occur on a chromatogram and of the spectrum of those chemicals that appear on the chromatogram which are going to be more concentrated in different compartments in the body. And it's all physical/chemical.

And things that you're already aware of, such as octanol water coefficients and vapor pressure and things like that, can predict whether something gets into the body. It's whether or not -- I mean when I'm -- when my eyes go across a page of data or I'm looking at a particular chemical, I'm thinking did somebody get exposed to this new, unusual chemical, something that, you know,

we haven't measured before in an inhalational way. I look at the vapor pressure. And right away, you know, I can tell myself whether it's likely or unlikely. But it doesn't mean that it's beyond the realm of circumstance even when it's unlikely that, you know, somebody could have done something unusual to get an exposure.

You're asking my personal belief. I think some of these physical/chemical kinds of pieces of information that are universally available, in many cases, that you can get off of places like the Hazardous Substances Database Inventory of Chemicals, you know, you can use. But, again, if you just take off chemicals that are even in that database and then you just pick the ones that are, say, high vapor pressures or high octanol water coefficients or some other physical/chemical parameter, you're going to end up with a lot of chemicals. You don't know that they're out there. You have to couple that then with use and then distribution of the chemical. If the chemical is even used in large quantities within industry, lots of industries are, you know, containing chemicals very well and they're not getting out into the public sector. So you have to know, you know, the complete history of the chemical.

I would encourage you though to ask the EPA that same question. Because they're doing this I think more on

a predictive basis than our team of laboratory analysts are.

REPRODUCTIVE AND CANCER HAZARD ASSESSMENT BRANCH CHIEF ZEISE: Joan.

DIRECTOR DENTON: John, I have two questions. One is -- you know, we're going to be doing about 2,000 samples, you're doing 2500 samples -- what is the total cost for your budget for biomonitoring?

And then the second question I wanted to ask is: Have you -- now you've gone over a series of, you know, five reports. Have you seen any trend information which might be helpful for California?

DR. OSTERLOH: There are certain chemicals that will fit in with a process that we've called the -- we don't like the name -- but a delisting process, where we're taking chemicals off the exposure report. Similarly to the nomination process, we have an advisory group that went through and set up criteria. And we are probably going to be removing some chemicals.

For instance, through three survey periods we haven't really detected 2,4,5-T -- the 2,4,5-trichlorophenoxyacetic acid, which is an old herbicide. And so it's unlikely that we need to measure that. However, it's part of another set of measurements, and so we probably wouldn't be measuring it. We're just

not -- we're not detecting it.

Have we looked at trends? We're starting to because we're getting our last set, our third survey set data done. We're looking at some chemicals now where we're seeing in smaller sets, like some of the perfluorinated chemicals, it looks like those chemicals' exposures might be dropping. And in part that's because we're moving away from producing them. They're no longer being produced as much. They're persistent but they're not as persistent as the older, say, organochlorine type chemicals.

We've done for lead obviously. And cotinine, environmental tobacco smoke, we're seeing large drops in environmental tobacco smoke.

So we're trying to do all of those. We just haven't come down. We're doing mercury right now. We're seeing a trend in mercury that looks like it may be going down. We haven't gotten all the final data for younger children.

So, given that that's sort of, you know, a result we haven't published yet, we don't really know what the final analysis is going to be. But we're working on those things. We're a small group. The exposure report itself is put out by me and three other people. And all of the analyses that are done for NHANES are done by a larger

group of folks obviously that produce the data.

But it will take us some time to get all of the trend data done and applying these knew criteria for taking chemicals off the report.

DIRECTOR DENTON: The budget --

REPRODUCTIVE AND CANCER HAZARD ASSESSMENT BRANCH CHIEF ZEISE: And the cost of --

DR. OSTERLOH: Oh, excuse me.

(Laughter.)

DR. OSTERLOH: The reason that threw me was because she hurried me up before and it was on my last summary slide. And so I don't have time to talk about it.

(Laughter.)

DIRECTOR DENTON: Now you do.

DR. OSTERLOH: I know.

Well, what we've estimated before -- the NHANES itself costs about $25 million to run for two-year survey period. And our analysis for that two-year survey period has been, in the last, about $8 million. It will probably be more than that this next time around. Probably a few million dollars more.

REPRODUCTIVE AND CANCER HAZARD ASSESSMENT BRANCH CHIEF ZEISE: So that's total for these chemical biomonitoring for the analysis for the support for going out into the field for the laboratory --

DR. OSTERLOH: The 25 million is out of the National Center of Environmental Health Statistics. They run NHANES. The 8 million is for the analysis.

REPRODUCTIVE AND CANCER HAZARD ASSESSMENT BRANCH CHIEF ZEISE: And does that include the field work for the --

DR. OSTERLOH: No.

REPRODUCTIVE AND CANCER HAZARD ASSESSMENT BRANCH CHIEF ZEISE: Okay. Thank you.

PANEL MEMBER SOLOMON: It seems that there are a couple of ways to go about looking for chemicals that occur in people, it looks like. One is to look -- you know, identify up front a list of chemicals that you're interested in looking for and look for them, which is a whole set of advantages. But the other is to potentially, you know, take some samples, look at the chromatographs, see where this, you know -- and start trying to figure out how to identify some of the unknowns, and then consider adding those chemicals to -- you know, to future surveys where presumably you'd be look for them specifically with the lower limit of detection.

I understand CDC is exploring that and doing some of that work, and I was hoping you'd talk about it a little.

DR. OSTERLOH: Which part of that? You suggested

two ways. I'm not sure I'm clear.

PANEL MEMBER SOLOMON: Looking for unknowns.

DR. OSTERLOH: Well, we're not. We're not --

PANEL MEMBER SOLOMON: Well, Larry Needham said you are.

DR. OSTERLOH: Well, no, we're not.

(Laughter.)

DR. OSTERLOH: We're not. We basically -- you know, I want you to understand that for any particular chromatogram that we get, it identifies a range of polarity, if you will, of chemicals. And when we're looking at the chemicals that we're looking at, we're looking for particular masses and particular mass ratios that are there. And we're only going to see those masses because we have the mass spec tuned to that. And that's the only way that we can detect really low concentrations.

Now, there's another way that you can run a mass spectrometer. You can look at total ionization and you can look for any peak that occurs, in which case you're looking for almost anything that comes through within that polarity spectrum.

So you might be looking at a polarity spectrum that doesn't include very lipid soluble substances and doesn't include very water substances but you're somewhere in the middle.

When you see those peaks, you can try to identify them against library matches, in other words libraries that are generated on either other mass spectrometers or other systems. A lot of times you only get an idea of what those chemicals are. You don't actually get a very good match that matches -- either are not there in the comparison library and then you're matching to something that's similar on a lower probability basis, or you're matching to something that's a derivative or a compound that's been derivatized and run through the mass spectrometer on some programmatic basis.

The real problem though is what I said earlier. If you look at total ionization spectrum, you're running at a sensitivity that's anywhere from ten to a hundredfold less sensitive than where you would be if you were running through in what we usually call the selected ion monitoring mode. And you probably won't be picking up those chemicals -- the chemicals that you're interested in.

Now, on the other hand, when we're -- and what Larry might be referring to in terms of your discussions with him -- within a series of chemicals or chemicals that are congeners of each other or very similar to each other, if we're looking, we can sometimes broaden the search and look within a mass spectral range, a very narrow mass

range and tune the mass spectrometer to see if a particular chemical that's coming out between two other chemicals is present. And sometimes we do that. So he might be referring to something like that.

Now, there are chemicals that we know also that are related to the chemicals that we are measuring, and we ask ourselves, "Hey, we could measure that chemical because it would probably come out" -- like I said earlier, we know what the polarity spectrum is, we know things like what the octanol water, you know, coefficient is. We suspect it will come out. We suspect it's similar to the compound that's next to it. And then we can tune the mass spectrometer exactly for mass that we'd expect and see if it's there. And we do that.

REPRODUCTIVE AND CANCER HAZARD ASSESSMENT BRANCH CHIEF ZEISE: A couple more questions.

Julia.

PANEL MEMBER QUINT: You mentioned in one of your slides that one of the comparisons that either you're making or could be made is with occupational exposures in the national data. And as you probably are aware, the American Conference of Governmental industry hygienists have done -- they have biological exposure indices for a number of industrial chemicals and have used those to compare with, you know, environmental monitoring for a

number of chemicals. And there's quite a bit of overlap, especially in your next set of chemicals where you have volatile organic chemicals. And I'm wondering if -- I don't know where -- you know, where that data resides, if it does reside anywhere. But I'm wondering if you've actually worked with NIOSH to sort of look at comparisons if they have data -- you know, biological exposure monitoring data that has been done according to those protocols developed by ACGIH to compare with the national data. It seems to me that that would be -- I don't know their methodology and how it differs -- it doesn't differ from yours. But I know careful attention is made according to when to take the sample in terms of toxicokinetics. So it seems to me it could be a rich source of data, you know, in order for somebody to make comparisons. I'm wondering if that has been thought of or if you've done it.

DR. OSTERLOH: No, we have done that with respect to the write-ups in the past for the BEIs. We've made some comparisons for some of the metals, for instance, in the past because those do overlap. And in some cases, they're the only place where you can find biological reference values. And they're from the occupational arena, obviously.

The VOCs we're finding a little problematic in

that there's some overlap, as you say, with ACGIH. The problem is that most of ACGIH's BEIs are based on metabolites of the various VOCs that appear in the urine. And we're actually measuring whole blood VOCs where they -- do have some information, but they haven't focused on those with respect to BEIs.

So, yes, I think that's a very good source. And NIOSH actually has a biomonitoring laboratory that they're hoping to grow. It's been around for a few years and they're using that coupled with a lot of their air exposure work.

PANEL MEMBER QUINT: Thanks.

REPRODUCTIVE AND CANCER HAZARD ASSESSMENT BRANCH CHIEF ZEISE: Okay. We've got four hands up. And so why don't we finish around the Panel, take the last -- maybe if you could try to compress your answers a little, because I think what we'll do is we'll try to break at 10:30. Okay? So if we could take the rest around the table and the one in the back.

So, Mary.

PANEL MEMBER KAVANAUGH-LYNCH: I understand there's statistical limitations now on reporting the CDC data by region. But I would imagine that scenarios where looking at just the California data from NHANES might provide some preliminary suggestions of intriguing places

to look in California specifically. Can you address that and whether that's been looked at or not.

DR. OSTERLOH: Well I can tell you what NHANES tells me. We can't -- we get the same database that everybody else gets. We contribute to it. It comes out in a public release. We analyze it for the exposure report. You could analyze it for making your own report.

The NHANES data when it's released is released to everybody. The things that we know that NHANES is concerned about with respect to sort of more micro looks at the data are two:

One is confidentiality. Once you get either too much information, demographic or analytical, combined, you can start to identify individuals. And the survey's taken up under the agreement of confidentiality. So they don't want to violate that.

The other part about it is is representativeness. And the data in any region from any smaller group of people and/or biased sample is not a representative of either the national data or necessarily the region that you're in.

So, when NHANES, for instance, needs a 30-year-old non-Hispanic black female, they may find that person in Illinois; they may find a 20-year-old non-Hispanic white female in California; they may find,

you know, a Mexican-American male who's 50 years old in Louisiana and then another one in California.

So they're not clustered so that they would be representative necessarily of California even though you've taken them from California.

Having said that, those are the limitations. Now, what NHANES is opening up to do is that they have a national data center that you can go to physically. And the way it's worked, at least my understanding so far, is that you can go into the data center; if you have like a memory stick or something of your data, you can take that in with you and you can take that out with you; and you can do your analysis within the confines of the data center but you can't take it away and do analysis.

So they are fairly restrictive. But they have a mechanism if you talk to them for looking at more secular types of data.

REPRODUCTIVE AND CANCER HAZARD ASSESSMENT BRANCH CHIEF ZEISE: Dwight.

PANEL MEMBER CULVER: Other than lead -- and this question grows out of my naivete. What programs, what public health programs owe their origin to the existence of the CDC data nationally?

And then I'd like to ask: Are there any programs, public health programs in California that owe

their origin to the existence of this data?

DR. OSTERLOH: Well, I can say I don't think that there are any particular chemically-based programs that owe their origin to the exposure report, at least that I'm aware of. There are -- we've been doing it now since 1999, and I don't know that any have been set up.

The blood-lead program was set up before we started doing the actual national exposure report. But it did rely upon data that was taken from one of the earliest NHANES surveys back in the late seventies for comparison --

PANEL MEMBER CULVER: So how do you justify then the expense of developing this data if it's not being used for public health?

DR. OSTERLOH: Well, I think what I tried to explain earlier was that it is being used. It has had an impact. And I think where we're seeing a lot of impact is actually in reevaluating the risk estimation process. I think the data itself, as I said, helps us focus on new concerns; and chemicals that we pay priority, either didn't know were there or it didn't think they were there in very high concentrations. The phthalates are a good example of that.

There's been extreme amount of inquiry with regard to the phthalates since they first appeared in our

report. And I'm not saying, you know, what the chemical effects of the phthalates are. But there's enough for everybody - industry, advocacy groups, and government - to relook at this and reevaluate it. It kicked off a large investigation and reanalysis by the National Toxicology Program.

So I mean I think we're sort of at the beginning of using biomonitoring data on a national basis in many respects.

The risk assessment process I mentioned, we're seeing a number of consultancy groups starting up whereby they're trying to do, what I call, reverse dosimetry - taking the levels in the blood and the urine and recomputing a dose based on pharmacokinetic parameters and comparing those to the traditional external dosimetric - to both determine whether or not we're close on those metrics and whether or not we might be incurring effects relative to those metrics.

REPRODUCTIVE AND CANCER HAZARD ASSESSMENT BRANCH CHIEF ZEISE: Okay. Ulricke.

You need a mic. Sorry. And then, in the back, if you want to come up to this microphone.

PANEL MEMBER LUDERER: Kind of regarding the selection of broad categories of chemicals to be included in biomonitoring programs, because other than some of the

phytoestrogens that are being measured, they're really are, I guess what I would call, industrial chemicals. And there's been a lot of concern, I would say, and growing appreciation in recent years that pharmaceuticals can also be environmental contaminants, and whether there's been any -- you know, whether there's any thought about including any pharmaceuticals in the biomonitoring program.

DR. OSTERLOH: Yeah, I think that's a great question. Yes is the short answer. The longer-winded answer is that we're looking at some -- right now developing some methods for antibiotics that get into the environment primarily from the raising of livestock, but also direct from human sources. That will be down the road when we get that. Also, with respect to estrogenic substances the concern is that ethynilestradiol as well as estradiol itself getting into the environment is probably one of the more important and potent of all of the estrogenic substances that are out there. And potentially -- we've been asked about that. We're not looking right this second at methods, but probably we'll be talking about that in the future.

REPRODUCTIVE AND CANCER HAZARD ASSESSMENT BRANCH CHIEF ZEISE: Okay.

MS. WILLIAMS: My name is LaDonna Williams, and

my organization is People for Children's Health and Environmental Justice. And we've dealt directly with CDC and ATSDR. So I've got actually a couple of questions.

One is -- as a community, our community was exposed to many toxins by Pacific Gas and Electric Company. And when we turned to CDC and ATSDR, there was literally no support. And as they begin to build this biomonitoring project and program, we community people have a major issue with the way that it's constructed because we understand it was mandated that it would be a scientific and technical panel that would be set up. But part of that problem is that it does not include community expertise.

So that as we begin to fill this program, ultimately it comes down to those of us that have been test -- that need the testing most to really determine how to move forward with this and how to be most effective. We're left out of the process. So then you're left with spinning your wheels and spending more millions and billions going back and forth trying to do it right.

And one of the major things that we had even with this is: Has CDC or those that are putting this together thought about reevaluating, number 1, that male model standard that they've used for what, a hundred years is outdated? I don't see any mention of that, and

reevaluating that as one thing to include the most vulnerable, which is pregnant women, infants, children, older ones, you know, those who's got already compromised health. I don't see, you know, where we're really considering those things, because ultimately we're going to have to.

The other thing is: How do you -- how does CDC and those that are leading this process plan on rebuilding trust within our communities that have turned to you in the past? We know we're exposed, we've got the illnesses that -- the data that already is out. You know, a lot of us, we may not have the degrees and, you know, the technical knowledge, but we have the common sense and the experience, in that we're sitting and surrounded by refineries, we look at the list of hundreds of chemicals and we see what potentially may happen, and then we have some of those symptoms; and then we come to you all and we get a report that comes back and says, "Oh, we don't determine that your illnesses are caused from this."

And these are real issues as we begin to put together this program that has to be addressed if it's going to be effective. And what I don't see is, I don't see those issues being out on the table.

And then last but not least, I as an African-American have a real problem sitting in workshop

after workshop and I hear comments like non-Hispanic compared to white, you know, non-Hispanic this or that. It's like you forgot about the blacks and the African-Americans. And if you look at all of our sites, the majority of us black, are being exposed at levels that are immeasurable in my opinion and they're being ignored.

So I'd like to see these issues on the table as we move forward.

DR. OSTERLOH: I'm trying to think of where to start. The questions that you posed are broad ones.

First, with respect to representation of special groups, and I would say secular exposures, there's two avenues that I'd like to bring up.

One is, if we're not helping you, I need to know that. And I will take that back.

CDC supports its state public health laboratory constituents, and we will work with the states when they identify within their areas areas of concerns that they would like to work up. And we will work with them epidemiologically and analytically. And we are doing that with respect to certain types of exposures, for instance, in agricultural communities within California.

The Biomonitoring National Exposure Reports, sort of going into another area that you mentioned, has some representational limitations. We focus on non-Hispanic

blacks, non-Hispanic whites, and Mexican-Americans. Those are the three major ethnic and race groups that we focus on. They are well represented.

But there are many groups that are not. And we get the same question, for instance, from Asian-Americans and various native American tribal groups; that while each of those types of groups are included into the exposure report and in the national survey, there aren't enough numbers to be nationally representative.

In the past, NHANES has tried to over-sample certain populations in order to get better representation within the larger national population.

And you mentioned pregnancy, which is very important, because has we know the focus for many chemicals is now coming down to gestational exposure being one of the most sensitive times.

And I think it's the '05-'06 survey for which we've analyzed some of the data; there was over-representation of pregnant women. Normally within a two-year cycle, there's only about 250 pregnancies nationally. The problem is they may not represent your particular community's exposure but I would encourage you to bring those through your state programs up to CDC, and we can help support those because we do that, when there are concerns in communities, as long as we're supporting

the constituent state operation. We have coupled with a number of investigations and we have with about 50 or so of these going on every year.

MS. WILLIAMS: Well, actually I wanted to address that, because we actually did bring to you all through our state program --

REPRODUCTIVE AND CANCER HAZARD ASSESSMENT BRANCH CHIEF ZEISE: Okay. So we're going to have take a break. But we can explore these issues more. We have an expanded discussion section in the afternoon.

So if you want to write your question down, we'll make sure that we cover it in the afternoon, you're certainly welcome also to participate.

MS. WILLIAMS: You will be here in the afternoon?

REPRODUCTIVE AND CANCER HAZARD ASSESSMENT BRANCH CHIEF ZEISE: Yes, yes.

DR. OSTERLOH: Sure.

REPRODUCTIVE AND CANCER HAZARD ASSESSMENT BRANCH CHIEF ZEISE: Okay. Thank you.

Why don't we take a ten-minute break. We'll come back.

We will be taking a later lunch. We do have a cafeteria on this floor.

If you do go outside, please be mindful of get back in through security, it just takes awhile. Thank

you.

So by that clock, at ten minutes till.

(Thereupon a recess was taken.)

REPRODUCTIVE AND CANCER HAZARD ASSESSMENT BRANCH

CHIEF ZEISE: Why don't we get started now.

Okay. If everybody could take their seats, we'll get started.

Our next speaker is Doug Haines with Health Canada. Doug is the Manager of the Environmental Health Surveillance Division in Canada's Safe Environments Program. He's been leading the Canadian efforts to develop and implement their biomonitoring program.

So, Doug.

(Thereupon an overhead presentation was Presented as follows.)

MR. HAINES: Thank you for the introduction. And I'm very pleased to be here.

It's past lunch time for me. So --

(Laughter.)

MR. HAINES: I want to talk a bit about our biomonitoring activities at Health Canada and provide a bit of context for how we put the biomonitoring together; and talk about the Canadian Health Measures Survey, which is somewhat analogous to NHANES in the U.S.; and a third piece to talk about the biomonitoring component of

NHANES -- of the Canadian Health Measures Survey. We call it CHMS for short. And it's quite impossible for me to disassociate one piece from the other, so I'll have to kind of segment my talk about that.

So if I can move to the next slide, please.

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MR. HAINES: The context for biomonitoring at Health Canada is really threefold: There's a regulatory context, a public health context, and also a context from an international perspective for our programs.

From the regulatory side, in 2007 the Government of Canada launched the Chemicals Management Plan, which is a plan to manage the 23,000 plus chemicals that were categorized over the past ten years and to move forward with the risk management of those as well as the assessment for those. And all of this is under the auspices of our Canadian Environmental Protection Act.

From a public health perspective, we see biomonitoring as fitting into our health surveillance activities. Also helps contribute to our Federal Contaminated Sites Program in terms of providing some baseline information on body levels of environmental chemicals for exposures.

Our tobacco control strategy where we'll be measuring cotinine in some of our projects to validate our

site-stream smoke exposures in some of the public health campaigns that are in place in Canada for tobacco control.

And also in terms of public health of our First Nations and Northern Health, first Nations for us I guess analogous to indian health in the U.S.

And internationally Health Canada -- or Canada is a signatory to the Stockholm convention on the control of persistent organic pollutants. And there are expectations that signatory countries will continue to monitor their exposures of their populations to these pops.

We also have activities undergoing under the NAFTA -- or the Commission for Environmental Cooperation under NAFTA, which are important, and international activities in the circumpolar region of the globe, of which Canada is partner in the Arctic Monitoring Assessment Program.

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MR. HAINES: Biomonitoring at Health Canada is really segmented into three major activities.

We have our national surveys and studies. And I'll we talking about the Canadian Health Measures Survey mostly today. But we also have another national study. And I won't call it a survey because it's not a national representative sample but one where we're recruiting 2,000 pregnant women from ten sites across the country. And we

will be collecting biospecimens from them at each trimester during pregnancy, cold blood at birth, human milk postnatally as well as meconium measuring from environmental chemicals.

The basic premise of this particular project is to look at what the reproductive health impacts are of contaminant exposure during pregnancy, but also use it as a way of getting national data on body burdens of environmental chemicals in pregnant women as they relate to their possible exposures to TS.

We also have another stream related to targeted population studies. One of our major activities is in the far north called Northern Contaminants Program, looking at environmental chemical issues, contaminant and body burdens in our northern populations, in the Inuit populations and the Cree. Inuit I guess is what you would commonly refer to as eskimos.

Historically we found that the levels of persistent organic pollutants in those populations were five to ten times higher than in southern Canada. And so we've implemented some monitoring programs in the far north which are tied in to the public health advice to help them reduce their body burdens and environmental chemicals without displacing them from their traditional diets, which they rely on living off the land.

We also have other projects looking at drinking water lead levels and deep body burdens on the children, whether they're leaded pipes or contributing to lead in blood lead exposures in kids.

The other stream that we have is what we call supporting research. And biomonitoring cannot just be national surveys of targeted studies, but also needs additional research to help us interpret what these mean in the long term. And so we're looking at some projects on biomonitoring equivalents looking at the tolerable or acceptable daily intakes and going back to see What would be an equivalent in terms of a body burden level.

We're measuring chronic exposures to lead across life span looking at three compartments in the bone through x-ray methods. Blood and serum as well. We're looking at whether bone is a better predictor of long-term exposures and what that means, and eventually possibly doing some national bone blood studies or surveys.

Looking at temporal variation in urinary phthalates in Bis A classifies it in pregnant women.

Our MIREC study as looking at one spot sample maybe three times during pregnancy -- or western pregnancy -- excuse me -- that is a spot sample actually indicative of what the exposures are, what the body levels are at any one time. These are very labile, quick acting

compounds, and the one sample may not be fully representative of what's happening.

Next slide, please.

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MR. HAINES: I'd like now to on the Canadian Health Measure Survey as a whole. The Canadian Measure Survey is a survey that's being led by Statistics Canada, which is our federal statistical agency. And it's in partnership with Health Canada ourselves and the Public Health Agency of Canada.

Go to the next slide, please.

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MR. HAINES: Overall the Canadian Health Measures Survey aims to address important data gaps and limitations, especially those that can't be obtained through proxy or self reports to questionnaires. So the next phase is to go and do direct measures on Canadians. And these include things such as fitness, height, weight, other metric measurements, and as well as a collection of blood and urine specimens.

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MR. HAINES: The parameters for the Canadian Health Measures Survey is:

We're collecting over a two-year period. And the survey was launched in March 2007, so we're halfway

through the two-year collection cycle.

It's to provide national or nationally representative estimates and not estimates that are -- that can be broken down by either province or municipality or community. So it's quite similar to NHANES in that respect.

It's an atypical design. So it's relatively clustered due to the cost of setting up clinics in different parts of the country to collect the biospecimens and the other physical measurements.

Canada is a fairly big country. We set up -- we've identified 15 sites, with about 333 respondents per site. It's actually going to be a bit higher than 333 because we're getting a better response rate than we expected when we launched the survey.

We have five age groups, from 6 to 11 to 60 to 79, covering most of the life span of the population. And our national estimate -- or our sampling frame also covers around 97 percent of the Canadian population. So it's not targeted first nations on reserve or people on armed forces bases, military bases or in institutions.

There are two components to the survey. There's a health questionnaire and home -- which is ending as a home interview. It's about a 90-minute questionnaire. And the direct measures are taken in a mobile clinic that

travel the country. We have two sets of clinics that travel the country. When one is set up, the other one is traveling to the next site and doing the prep for the next site.

The budget for the overall Canadian Health Measures survey is $35 million -- 35 to $38 million over six years. And this I'm talking about the first cycle.

The biomonitoring component on the Canadian Health Measures Survey is around $6.2 million, of which about 90 percent of that cost to my program is for the laboratory analysis buy-in. So most of that money is going for the actual laboratory analysis. I'm quite lucky, as I don't have to pay too much for the infrastructure because I've hopped on to a national survey infrastructure to do that.

Next slide, please.

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MR. HAINES: The Canadian Health Measures survey through its development phase consulted through and established many processes. And Statistics Canada led those developments. But Health Canada and Public Health Agency of Canada are partners both in funding and in content development.

We've consulted -- or at times consulted with NHANES in terms of how they've done sharing of

methodologies and so on. They've developed an Expert Advisory Committee, which advises on the content of each phase of the CHMS, Canadian Health Measures Survey. There's a Lab Committee. There's a Data Analysis Advisory Committee.

Very important is the Research Ethics Boards. And I think there was a question earlier about measuring for unknowns. And our Research Ethics Board probably would not allow us to a pre -- or a post hoc measure for unknowns unless we had a specific question or a clause in our consent that would allow us to do that. And that was not asked in the first time.

However, we are doing biospecimen storage, which will allow us to measure other things in the future.

Next slide, please.

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MR. HAINES: The process of the Canadian Health Measures survey in terms of sampling, Statistics Canada developed a national sampling frame based on the 2006 census. So that was actually one year -- the census was less than a year before the launching of the Canadian Health Measures Survey. So the census meant that we were using a fairly timely and recent sampling frame.

They've selected clusters and developed stand schedules and selected households within these clusters.

There are 15 clusters across the country. Within the households they've selected the respondents, the book they interview. They do an in-home interview where they ask for consent to participate in the clinic. And then the respondent will visit the clinic to have their measurements taken there. All this is done through informed consent.

Next.

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MR. HAINES: The questionnaire, which is implemented in the household, in the home, covers numbers of areas from health status, nutrition and food, medical use, health behaviors, socioeconomic information, and environmental factors.

The environmental factors are asking some of the household characteristics: Age of home. We're looking for a grooming product use, some pesticide use.

There's also -- in the nutrition and food portion there's fish and meat consumption that it asks there as well as water consumption.

And in the environmental factors section we're also asked about some of the pesticide use in the home.

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MR. HAINES: The physical measures that are collected in the clinic include general anthropometric

measurements of height, weight, circumference, and skin fold measures, so that they can get an idea of -- or use those in developed adiposities, BMIs and so on -- body mass index.

A measure of their cardiorespiratory and physical fitness. There's a fitness test given in the clinic.

Physical activity. At the clinic they're given a pedometer. They carry the pedometer home for a week and then mail it in.

There's an oral health, a dental exam that's administered in the clinic.

And then the blood and urine measurements are also collected in the clinic. Blood measures are for fasting individuals. And if they refuse to fast, we try to get them to not eat in the morning but schedule the clinic visit in the afternoon, so we get close to fasting with them.

And so the environmental measures -- sorry -- for the blood measures we collect environmental chemicals. We do markers on nutritional status, diabetes, cardiovascular disease such as blood lipids and so on, a few markers of infectious disease, generic blood chemistry profile, and storing biospecimens for DNA samples for future use as part of a DNA bank.

Urine measurements, we're also collecting

environmental exposures, iodine related to our nutritional factors, and microalbumin related to diabetes measures, and creatinine as a collection factor is for some of our other measurements that are both environmental and other health measurements as well.

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MR. HAINES: From the clinic there is a wet lab at the back of the clinic to process the biological specimens. Then the biological specimens are stored for a few days and then sent to three different laboratories.

There's a Health Canada laboratory in Ottawa that the specimens are sent to for the chronic disease and nutrition factors, markers that are being measured.

Our National Microbiology Lab in Winnipeg is where we'll be storing and setting up our biorepository for storing the biospecimens for long term. And they're also the lab that is doing the -- that are doing the infectious disease measurements.

And then for the environmental biomarkers and then the environmental chemical measurements we're using one lab, which is the Centre Toxicologie Quebec, which is CTQ for short, which is the Quebec Provisional National Toxicology Center. A very good lab as far as we're concerned.

And one of the challenges that we have from the

environmental chemical measurement's point of view is to try to limit the number of labs that you send material to. It's expensive to ship biospecimens that are tracking issues as well to track where the specimens are going to. It's just more expensive and more operationally difficult the more labs that you have.

The next slide, please.

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MR. HAINES: We are reporting results back to respondents. At the end of a clinic visit, which is in the mobile lab, the respondents receive the results of their physical tests, in other words this is your height, this is your weight, this is your blood pressure. But there are none of the environmental chemical measurements obviously at that time.

However, selected lab results are sent to respondents 12 weeks after the clinic visit. Now, we say with prior consent because, for example, for blood lead, one province in Canada lead is a reportable measure. And so we have to receive special consent from our samples in the Province of Quebec for that particular measure.

Other measurements also are -- sorry. Lead and mercury in Quebec are the two. Other provinces are generally sent their results.

We're only providing freely, I guess you could

say that, the results for lead, cadmium, and mercury to the respondent. And that's because we know more about those that -- we know what advice to give to the respondents if they have a higher value. We know what to do about these.

The other measurements, which I'll go through, there are no tissue guidelines, body burden guidelines, reference doses and so on. And so we're not freely reporting those to the individuals. However, if the individual requests those results, they will be provided to them.

And we have an early reporting protocol in place for lab results that are beyond threshold values. In other words if your blood lead is over X amount which is a threshold value, there will be a letter sent to the individual advising them of their value, and that with advice to talk to their health professional or health practitioner for further advice.

Neither Health Canada nor Statistics Canada can provide medical advice to individuals.

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MR. HAINES: I'll now slip into the biomonitoring component of the Canadian Health Measures Survey. And I'll move to the next slide.

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MR. HAINES: Our three primary objectives of the CHMS, the biomonitoring component of that survey, are to establish nationally-representative values for a range of environmental chemicals in Canada. This is the first ever national survey of this range. We had one previous in 1979 where they measured lead in the population.

We also want to provide a baseline, in other words levels today so that we can track emerging trends, and also to allow us to compare data with either sub-populations in Canada where targeted studies are done - they will at least have a national reference range, I guess, that they can be compared to - or with other countries. And that's important for us to kind of -- to gauge where Canada is vis-a-vis Europe, other places in North America and other parts of the world.

And the Canadian Health Measures Survey will also provide opportunities to explore relationships between environmental chemicals, other physical measurements - for example, blood pressure and blood lead, is there any relationship - and self-reported information as well, medical use or pesticide use in the home and whether those can help us identify whether there are particular trends or patterns in pesticides -- or sources of pesticide exposures.

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MR. HAINES: Back in 2003, we were asked to quickly identify what we would want to include in the Canadian Health Measures Survey in terms of environmental chemicals. So we held an expert workshop in November 2003.

We used the NHANES, which was the second report, as our base of discussion with the experts that came from across the country to that workshop, and asked a number of questions and applied a number of criteria to the discussions.

And we look at -- the criteria that we looked at were public health considerations, whether there was known or suspected risks or health effects of those environmental chemicals, whether there was a need for public health action, and whether there's public concern.

And public concern for the health actions can be two different things nonetheless; something that we considered as we looked at what to measure.

We also looked at evidence of population exposures, either through other studies that were done in Canada or elsewhere.

The criteria of feasibility of field collections of biospecimens and the burden on the respondents. In other words, is this feasible to do this in a national study? And how much burden are we asking of the

individuals? We can only collect so much blood from somebody. And so we have to be cognizant of that.

Do laboratory methods actually exist to do these things? Are they valid? Are there standard methodologies, lab methods to do these measurements?

We looked at other surveys, other than Canada, internationally. Were we consistent?

And, finally, we looked at cost. And cost is a driver. For example, through our first cycle, we considered dioxins. But to do individual measurements of dioxins, it's about 800 to $1,000 a person. So if it's approximately a thousand people, it's a million dollars. So we knocked that out but we added other things in, which just gave another trade-off.

So the selections of environmental chemicals is really a blend of art and science. And I'm not sure that science -- pure science will tell you exactly what to measure. They can help you, but there are other considerations as well that need to be considered as you select environmental chemicals for these kinds of surveys.

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MR. HAINES: But these are some of the rationales that we used for the selection of environmental chemicals and some of the uses as well of what we'll do with the information.

We know that, for example, some of our heavy metals are fairly well known neurotoxins and we know the health impacts, and we have pretty good ideas of what toxic levels are in populations.

What we didn't have in Canada is any national data, any national baseline of values. So that's one of the rationales that we use there.

For some of our plasticizers such as phthalates Bisphenol A -- and Bisphenol always a bit -- about the time when we look at that now four ago -- four or five years ago. They're a high volume use. They're found in all sorts of consumer products. And we needed to provide more information to inform both the risk assessment and perhaps the risk management issues on the side. And Bisphenol A's being partly risk managed in Health Canada. More recently Bisphenol A has been banned in baby bottles.

But we still need more Bis A data. So this will help provide some of that.

In terms of our current use of herbicides and pesticides, which has the organophosphates, phenoxys and pyrethroids, the Pest Management Regulatory Agency, which is affiliated with Health Canada, is doing some reassessments of these compounds. And they were interested in having some more population-based human exposure data and human-level data to assist them in their

reevaluation of these compounds.

And I can't say that I understand fully how they do these things because I'm not a risk assessor at all.

And then we have some classic compounds, more historical legacy-types of compounds, which are our PCBs, polychlorinated biphenyls, our organochlorine pesticides, which are still found in Canada. Although the PCB use is being grandfathered out. But the organochlorine pesticides have been largely -- or were largely banned from many years. And they certainly persist. And they are found in our northern populations as well.

So that's some of the rationale for why we've chosen some of these compounds.

Next.

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MR. HAINES: This slide really shows the compounds that we're measuring; the matrices, blood, urine, plasma, that we're measuring in the Canadian Health Measures Survey; and the sample sizes; and the age groups.

We're not measuring everything on everybody. And we made some decisions on some of the compounds to not including children. Part of that was due to trying to contain costs. Part of that was also due to, certainly for the organochlorine pesticides and PCBs, is that they bioaccumulate in the lifespan. They generally tend to be

higher in the older age groups, and so we decided not to do them in the younger age groups.

Next slide, please.

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MR. HAINES: What we propose is -- data analysis that we're proposing on doing over the next several years, we want to generate, as I mentioned earlier, nationally representative data, normative data, very similar to the exposure reports that CDC does using the NHANES-derived biospecimens.

Look at trends and comparisons, Canada -- internationally Canada, with some of the measurements that we have in the past and perhaps also some of the geographic trends that we have with other regions of the country.

We want to look relationships between measures, exposure sources and blood or urine concentrations, and between the biomonitoring measures and some of the health outcomes that are being measured in the Canadian Health Measures Survey.

And we also want to look at quality assurance. That's being done through the life span of the survey. And that's something that if -- when develop these biomonitoring initiatives, we have to have a pretty strong quality assurance component. You need to make sure

that -- well, we need to make sure that the data are valid, that they're defendable, and that they say what they say. And that many risk management decisions will be based on the data that you're collecting. So that's pretty important, to have that component built in.

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MR. HAINES: We just received in -- well, it was just announced in April in the federal government budget that the next cycle and ongoing cycles of the Canadian Health Measures Survey has been funded. So that was a coup, I guess we can say, on our part. And so now we're just starting the development of content for the next cycle of the Canadian Health Measures Survey. So while we're trying to get the first one done, we're developing the content for the next cycle.

So we initiated a consultation in May. And it's a questionnaire-based consultation, which will close June 15th, which is next week. We've distributed questionnaires within Health Canada, within other federal departments and agencies.

Within Health Canada we also have what we call a monitoring and surveillance network, which are made up of different branches of Health Canada and different programs. And we come together and talk about these things.

We've also distributed through our Federal/Provincial/Territorial Committee on Health and Environment, which has representatives from across the provinces and territories.

The Chemicals Management Plan has a stakeholder advisory council made up of provincial reps, academic reps, non-governmental organization reps and industry reps. And so we're working our questionnaire through that network.

And we're looking at the -- once we close the questionnaire phase of this, which is next week, we'll review the information that we've received, assess the results of the questionnaire using our selection criteria, largely the same ones that we used before. We'll work towards finalizing candidate substances by the end of July to the first week of August. Although I think I can probably push that into a few weeks beyond that.

But that's basically our time schedule.

One thing I have to highlight is that this Cycle 1 of the Canadian Health Measures survey started at age 6 and went to age 79. Our next cycle and one of the commitments that was made and one of the requirements for funding of the second cycle of CHMS was to include younger individuals in the Canadian Health Measures Survey. So we're working with Statistics Canada to see how far down

we can go. We expect it will likely be a sample of 3 to 5 year olds, possibly 2 to 5 year olds. That's still going to be -- needs to be decided and worked out with Stat Can.

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MR. HAINES: Well, this is our survey plans and how we cycle the surveys and how we expect to cycle the surveys in the future. So that our first cycle is now in progress, and we expect to have data and results reported out by spring and summer 2010.

Our next cycle of the Canadian Health Measures Survey will actually start end of summer 2009, which is why we have to have our content in a year ahead of time, so that it can be worked into the operation design of the Canadian Health Measures Survey. So there's an overlap of a year. Content design overlaps with the second year of the content collection of the survey collection. So it makes it fairly challenging for us.

One thing I have to also mention is that first cycle of the Canadian Health Measures Survey took many years to develop. The concept of the CHMS was done -- was developed in 2000, 2001. The full funding was obtained through federal appropriations in 2003 for the first cycle. But it still wasn't enough to do a full survey, which is why we're buying pieces into that.

The field testing and the pilot testing was done

in 2005, 2006. And the survey hit the actual collection in the field in 2007. And the results will come out in 2010. So it's a ten-year kind of development cycle -- ten year from content development to results. So something to be cognizant about.

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MR. HAINES: So in conclusion, it's the first comprehensive national biomonitoring study that was done in Canada. And it's one piece of a number of biomonitoring activities that we're doing. It will provide baseline for temporal geographic trends and allow us to do some comparisons in Canada and internationally. We see it as a significant resource for future research and monitoring. And I think it can inform where research can go, not necessarily be the research vehicle itself.

There are multiple uses and applications of the end results, and some things that we hadn't even thought about now, I'm sure. And we're planning the second cycle of CHMS.

And if you're looking for more information on the last slide, I've put some of the websites that you can obtain a bit more information on the Canadian Health Measures Survey through the Statistics Canada website or MIREC, the Maternal-Infant Research on Environmental Chemicals. And I think I have to update that to you

because between last Friday and today the website has changed. And our Northern Contaminants Program, which is done in partner with the Indian and Northern Affairs Canada, which is another federal department, has all the previous reports that were done there, are on that particular website.

So that concludes my presentation on the biomonitoring activities.

(Applause.)

REPRODUCTIVE AND CANCER HAZARD ASSESSMENT BRANCH CHIEF ZEISE: Thank you.

So now we'll start the question and answers.

Asa.

PANEL MEMBER BRADMAN: Almost more of a comment than a question.

I was interested in Canada's interest including younger children. And I'd like to hear a little bit more about that. And perhaps that also can be up for discussion this afternoon about the CDC program and perhaps California's future program.

What barriers have you seen to implementing that? And I assume you're going to focus on urine for that. But if you could talk a little bit more about that.

MR. HAINES: Canada's been very interested in children's environmental health. The reason we didn't

include it in the first cycle of the CHMS, our initial focus testing with parents was not -- we didn't think that we could incorporate other blood testing for kids at that time. It was really kind of a parental acceptability at that time. But since we've gone into the field in the Canadian Health Measures Survey, we're finding that there's actually more acceptability now.

We also didn't want to overwhelm the samples. So if you put kids in, we only had so much money, you take away from another age group.

We also wanted a success. So that if we weren't successful measuring kids in the first cycle of the survey, it becomes harder for us to make the case to get ongoing funding for the Canadian Health Measures Survey. So it's a bit strategic on that part. So there's a number of issues that came into play for that.

Now, what we're able to do is convince both Stat Can and our political master that we would like to do kids. And one of the criteria for funding that we received was to include kids in the next cycle of the Canadian Health Measures Survey. Remember, this is just not just a biomonitoring -- environmental chemical biomonitoring study. It's also a study of general health as well. So there may be interest in nutritional and other markers in kids.

So that's generally how we went about trying to get -- incorporating kids into the CHMS.

DR. KOLOSSA-GEHRING: Maybe you said it and I didn't catch it. But in the different cycles is the study cross-sectional? So do you analyze the same people again in the different cycles or is it always different?

MR. HAINES: No, this is a cross-sectional survey. So there's no longitudinal follow-up of respondents. There are questions being asked to those who can consent of linking to their administrative data files -- health data files. But it's not a measurement per se. It's really looking at long-term linking to administrative data bases.

We're looking at other vehicles for longitudinal follow-up. We've been very interested in a Canadian equivalence of the National Children Study in the U.S. But it's not come to bear so far.

REPRODUCTIVE AND CANCER HAZARD ASSESSMENT BRANCH CHIEF ZEISE: Michael.

PANEL MEMBER WILSON: Yes. Douglas, thank you very much for your presentation and for joining us today.

And my question is -- under the Canadian Environmental Protection Act, CEPA, Health Canada and Environment Canada are working on categorizing existing chemicals that are used in Canada. And I think there's

about 23,000. They've identified about 4,000 chemicals of concern now. And I'm wondering if -- and maybe it's too early in your program -- but if there's discussion between the agencies on using that information, developed under CEPA, as part of the biomonitoring program?

MR. HAINES: There are discussions. There are actually 66 that we call early childhood substances. And there are about several hundred to a few thousand that are, we'll call them, medium priority substances.

One of the big challenges from the biomonitoring perspective is really selecting what to measure. And that some of these compounds we knew -- although they've been categorized, they haven't been fully risk assessed, for one thing. There's always a lag between what you can -- what you wish to biomonitor and what you can biomonitor. And also a -- should we biomonitor everything? And I think there's some -- what you're asking is a really difficult question to answer. So which is why we're going through this questionnaire, through these dialogues with different groups and we're having internal discussion. And Environment Canada is part of that discussion as well.

I looked at the first Canadian Health Measures Survey biomonitoring component. And out of the challenge substances, out of the 66, there may be 3 that are overlapping somewhat. And if I look at the -- what we

call our second previous categorization and evaluation we call priority substances list, we have about 11 compounds that are being measured in the Canadian Health Measures Survey that are consistent with this previous assessment.

So I think it's going to be really hard to make some decisions and to pull in what people think we'd want on this Canadian Health Measures Survey.

The other thing we're doing as well, if I can take a step back from the biomonitoring piece itself, is looking at, is biomonitoring actually the best way to performance measure or to monitor these things? Could be that we're better off measuring and -- doing environmental measurements for some things, either -- release inventories for other things. It could be we measure some of the action that we take. In other words things that are nonpersistent and they -- you know, once we take them out, they're gone. It could be that just measuring or monitoring the market use and removal may be better than actually measuring in the human itself.

So this is a discussion that we've had within Health Canada and within Environmental Canada as well.

PANEL MEMBER SOLOMON: Can you talk a little bit more about how you did or if -- the degree of which you took into consideration Canada's specific factors in terms of industries or sort of patterns of chemical use in the

country to, you know, generate hypotheses for testing within the survey of chemicals that, for example, might be expected to be higher in Canada or lower. You know, an example that comes to mind is, at least to my knowledge, MMT is used in gasoline in Canada, so one might -- since elevated levels have been found in pigeons in Quebec, so one might expect that manganese would be an interesting chemical to look at because the concentrations might be higher.

So did you look at things like that? And if so, how?

MR. HAINES: Well, we did include manganese in the Canadian Health Measures Survey precisely for that reason, is to provide some more input into the MMT or the manganese risk assessment.

Some of those, like as I mentioned earlier, are historical. PCBs are still in use but declining -- but their use is declining. But because they're persistent, we needed to continue to measure those things.

I mentioned earlier that some of the pesticides -- the current-use pesticides are up for reassessment and reevaluation. There's interest in the program priorities to get better exposure information there. You know, these are broad-use compounds across the country.

Bisphenol A at the times -- if I recall, in 2003 was kind of looking ahead as a future item. It's not a future item anymore, but that was one of the rationales why we included it there at that time. So we didn't look at high production volume kind of activities the way that I think you're suggesting. But most of what we're measuring are things that are of interest, either from a public health or from a regulatory perspective.

If I put maybe kind of a bit of a light on the second cycle of Canadian Health Measures Survey, some of the things that I'm interested in are still old. I'd be interested in taking some of the old organochlorine compounds out but include dioxins in. The reason for that is that we have no national records values, and there is an Agent Orange issue in Canada that we had nothing to compare against.

I'd still be interested from a public health side of things to do speciated arsenic in urine, because there are pockets across the country where there's natural elevated arsenic in drinking water. And so it would be interesting to get a national perspective or national reference values for which we can compare those types of measurements.

So some of the rationale of how we can approach some of these things.

REPRODUCTIVE AND CANCER HAZARD ASSESSMENT BRANCH CHIEF ZEISE: Ed.

CHAIRPERSON MORENO: Yes, I was interested in hearing whether you were able to take into account some of the -- or how to say this -- divide some of the questions in the questionnaire in the home survey to correlate with the sampling of what occurs with biomonitoring, and whether you foresee an ability to in the future use that coordination to better interpret the results of biomonitoring to arrive at some public health recommendations or policies?

MR. HAINES: Yeah, through the -- we did try to do that in the first cycle. We included -- it included grooming product uses mostly around to help us identify exposure sources to phthalates through grooming products, you know, soaps and shampoos and so on.

We asked some questions of age of home. Maybe that will help us identify lead as a source of -- or older homes as a source of lead exposure.

We looked at fish consumption and asking the amount of fish they're consuming so that we can possibly relate that back to mercury levels.

So that's some of the -- well, also the some of the pesticide use in the homes. In other words, do you use pesticides for -- you know, in the home for whatever

reason?

I have the questionnaire with me. I'm certainly willing to share it. And it's also on the Health Canada site -- or the Stat Can site as well.

I think though the questionnaire will need to evolve to be more precise in the future. This was our first time. So we'll see how useful it is this time, and may need to refine it as we go along.

We're not the only players on the CHMS right there. There's a lot of -- we have only so much space, so you can't be fully detailed and only focus on your own issue on that.

REPRODUCTIVE AND CANCER HAZARD ASSESSMENT BRANCH CHIEF ZEISE: Diana.

MS. LEE: Just a really quick question about your question.

Are they validated exposure-related questions?

MR. HAINES: I would say that look at the overall questionnaire, which I have something like 20 or 27 components to it. Some are validated and some are not so validated.

REPRODUCTIVE AND CANCER HAZARD ASSESSMENT BRANCH CHIEF ZEISE: Rick.

CDPH ENVIRONMENTAL & OCCUPATIONAL DISEASE CONTROL DIVISION ACTING CHIEF KREUTZER: Just a quick protocol

question. And it would apply also for the CDC NHANES ones.

When you determine that in a given cycle you'll add chemicals to look at, do you automatically then go back to bank specimens to measure those same new chemicals in the old samples? Or how do you, you know, kind of view this notion of using the stored specimens?

MR. HAINES: The bank specimens are bank for multiple use from chronic, infectious, and environmental. So there will be an oversight panel for the bank samples, and then with submissions to access those to do different things including measuring environmental chemicals. So it would be in some cases interesting when ten years from now, if we measure something new, to go back and measure something old, something in the old samples. So Compound W ten years from now is a new compound. Interesting to go back and see if we can measure it in the old samples. That's something that we've thought about, but we haven't systematically said we'll do this and that and this, you know, in the past or the future.

In terms of cycling compounds in and out of Canadian Health Measures Survey, I mean that's why we're doing this set of consultations. I would hate to see the CHMS as being static and this is the only thing you measure, you know, all the time. I think you can measure

some things at one point in time in one cycle and maybe not measure that one in the next cycle but measure something else, then go back in a future cycle and then reintroduce something that you've taken out. That way it's a way of containing what you can do, still get monitoring over time, and get some meaningful results as well.

REPRODUCTIVE AND CANCER HAZARD ASSESSMENT BRANCH CHIEF ZEISE: Just one last question.

DR. CLARK: I'm Dr. Henry Clark, Executive Director of the West County Toxics Coalition in Richmond, representing one of the oldest environmental justice organizations actually in the world. We've been around for about 25 or more years and involved in this process.

Just one question I want to ask here. I know we're talking about biomonitoring and, you know, designating different chemicals to be on the list as far as concern. But what concerns me at this particular point is the issue of -- for instance, we know that lead is a problem and we've been trying to get lead out of the paint and other sources, as well mercury. Okay, mercury out of the water and the fish contamination. But what I'm finding is on the one hand we're trying to ban these different chemicals, but then on the other hand they're coming right back around. So how do we plug that loop up?

For instance, with mercury, okay, we're trying to get mercury out of the water so forth. Yet we got these new light bulbs that contain mercury.

Okay. We're trying to get lead out of the paint and other sources. Yet we have products, say, maybe coming in from Mexico or other sources with lead in it.

So it seems like if we don't close the loop there, we're defeating our purpose, you know. Especially on the mercury stuff. You know, we talking about eliminating mercury out of the water and so forth. We're coming back with mercury in light bulbs and mercury in those children's shoes with the light on them. I mean what type of nonsense is this? If we're serious, how are we going to the close -- when are we going to close up the loop?

REPRODUCTIVE AND CANCER HAZARD ASSESSMENT BRANCH CHIEF ZEISE: Thank you. We'll take that as a comment. And we do have regulatory people in the audience that have heard it. So thank you.

I don't know if you have anything to add.

MR. HAINES: I do have a comment. I mean it's a legit question to ask. But if we don't measure it, we don't actually know what's happening. So this is why we're interested in Canada in measuring environmental chemicals, including mercury, in the population, to ensure

that our risk management strategies and our interventions are actually working. So that if new things are being introduced, then we'll have a better chance of getting a signal the public is being exposed or in an increasing fashion if those new things are actually causing exposures in people.

If our public health and also our environmental controls are working, we should be able to see declining exposures. And we've done that and I think has been well identified in terms of lead and blood lead and removal of leaded gasoline in Canada and in the United States as well.

So it's one tool among many.

REPRODUCTIVE AND CANCER HAZARD ASSESSMENT BRANCH CHIEF ZEISE: Thank you.

Okay. Thank you.

MS. WILLIAMS: Can we ask one more question?

REPRODUCTIVE AND CANCER HAZARD ASSESSMENT BRANCH CHIEF ZEISE: I'm afraid in order to --

MS. WILLIAMS: It will only take a minute.

REPRODUCTIVE AND CANCER HAZARD ASSESSMENT BRANCH CHIEF ZEISE: Yeah, I'm --

MS. WILLIAMS: We're trying to be -- we need to understand that one question.

REPRODUCTIVE AND CANCER HAZARD ASSESSMENT BRANCH

CHIEF ZEISE: But I would like to postpone question -- if you could write it down, because we will be having a discussion in the afternoon. And we --

MS. WILLIAMS: I just wanted to ask, your areas that you're choosing to do your testing with the pregnant women and in those areas that you mentioned earlier, did you consider environmental justice issues when you chose those areas?

MR. HAINES: Not directly. However, within the Canadian Health Measures Survey I was asking questions about ethnic origin and ethnic background. About 15 percent of the Canadian population are new Canadians actually. So we're including that in the Canadian Health Measures Survey.

We also have a separate biomonitoring program for first nations and aboriginals south of 60 -- south of the 60th parallel in Canada, which are more community specific. And it's outside of the Canadian Health Measures Survey but targeted in that fashion.

And the third piece that we have is one in the northern population. There are only about 125,000 people that live Canada's north north of 60. But they are exposed and found to be exposed because they live off the land to levels that are five to ten times higher in terms of the older persistent organic compounds. And so we

targeted our efforts there.

So it's not an environmental justice perhaps as defined in the United States, but we are working at identifying groups and working with groups to do this kind of work.

REPRODUCTIVE AND CANCER HAZARD ASSESSMENT BRANCH CHIEF ZEISE: Thanks.

Thank you.

Now we'll move to a presentation from the German program. Marike Kolossa and Kerstin Becker of the German Environmental Hygiene Department. They'll be making a joint presentation.

Both have been with the German Environmental Hygiene Department for many years.

Marike leads the German biomonitoring program and is a member of the EU expert team that supports biomonitoring. And she also chairs the OECD Environmental Disrupter Testing Program -- Testing and Assessment Task Force.

And Kerstin is a senior scientist with the Department. And she's heavily involved in both the German and EU biomonitoring program.

DR. BECKER: Thank you for inviting us again. And thank you for giving us the opportunity to show and discuss the German Environmental Survey.

The next slide, please.

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DR. BECKER: When did we start in Germany? About 30 years ago we had several issues on the agenda, like a hundred cows dying in the vicinity of lead works. We had lead in children near a battery plant. And we had lead in blood of children near smelting works at that time. We didn't have values to evaluate the data we measured in the blood of the children, for example, for lead and we had no comparable data.

And the scientific challenge of course was to realize that we do not have to protect only the environment but also the human in the environment, the human being.

And other challenges were of course the internal and external exposure, to find exposure sources, to define the health impact and to define policy measures.

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DR. BECKER: So after -- let's say, in the late seventies we start to implement the German Environmental Survey. We implemented it as a cross-sectional study. And the main target was to find the background levels and the exposure of the general population. And we included several media and parameters to find exposure sources and exposure pathways for the risk assessment and the

definition of policy measures.

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DR. BECKER: So we had 20 years of GerES. We started in 1985 to 2007 in adults. In the nineties we realized that we should include children and included 700 children -- 730 children from the families -- belonging to the families we analyzed for the adult population.

And we -- again in 1998 we analyzed adults. And what we are doing now is the evaluation of GerES IV, which is a GerES only for children. We made field work from 2003 to 2006.

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DR. BECKER: So this is what we have today. We have health related environmental monitoring. And it is based on three basic components, basic modules:

First is GerES of course.

The second is the environmental specimen bank. This is a specimen bank where we store samples from young adults, from students, from different sample sites in Germany. And this enables us to do retrospective analysis.

And then we have the module of specific studies. This sounds -- I mean it's not very specific. But we think we are going to make a feasibility study for a cohort which will include hopefully -- will include

mothers and children -- pregnant mothers and children.

All this health related environmental monitoring is part of the action plan, environmental and health, which was implemented in Europe a few years ago. And it's also part of the political commitments with the Ministry of Environment and Health and part of the environmental monitoring which is a task of the Ministry of Environment and Health.

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DR. BECKER: This is the population -- it shows the sampling locations that we had for GerES. They were chosen representatively all over Germany according to the community size. And we analyzed 1,790 children from 3 to 14 years. They were chosen representatively to age, gender, community size, and region, which means East and West Germany. East Germany is the former GER.

Next. Please.

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DR. BECKER: And this is the time frame for GerES 4. We started with the planning in 1999. We had a pilot study because we wanted to check if we can use the instrument we used for the adults also for children. And did a pilot study with 600 children. Then in 2003 we started field work. Chemical analysis we finished in 2008.

What we are doing now is the basic evaluation. 9/2008 we will publish a public use file, which can be ordered by other scientists to include evaluations.

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DR. BECKER: The team players involved in the survey is -- okay, this is the German Environment Agency. Then we have -- what we analyze is a subsample of the German Health Survey for Children and Adolescents, which are where they analyze a sample of 18,000 children, age 0 to 17 years. And we take -- randomly selected about 1,800 children out of this sample.

We have a Scientific Advisory Board for both surveys. And different to what they do in NHANES and, as I understand, in the Canadian survey, we have to make calls for laboratories to attend there. So we don't have a national laboratory as in NHANES. And that's one -- this work is done by our agency and -- yeah, it supports competition.

(Laughter.)

DR. BECKER: What we do with our results is we report it in case that they belong to the nutrition pathway to consumer products due to our complementary involvement with fellow agencies.

Next, please.

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DR. BECKER: The main instruments used is human biomonitoring, ambient monitoring, and questionnaires. And we analyze biological, physical, and chemical pollutants.

Next, please.

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DR. BECKER: Instruments: HBM. We analyze blood. We analyze only metals and persistent organochlorines in blood. Because we analyze children and we don't come for so much -- such as big blood sample from the children, we can take two milliliters for the children from 3 to 6. And older than 7 we have four additional millimeters to analyze the organochlorine components.

Then we do several metals. And the substance are or more or less comparable to what the other services do. But Marike will come to this later again.

Okay. Next, please.

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DR. BECKER: As I said, we try to include ambient monitoring as good as it goes. And we analyze house dust, drinking water, and indoor air.

Next, please.

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DR. BECKER: And we have questionnaires: Indoor and outdoor environmental issues, health information,

socioeconomic status, food consumption, exposure relevant habits, and so on. And it should be comparable to the other service.

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DR. BECKER: Field work was done, as I said. It was cooperation with the National Health Survey. We have three field teams. We have a randomized sampling sequence. The participants visit an examination center to give the blood samples. They are visited at home to collect environment samples and living samples. And they put a lot of emphasis on internal and external quality control, because here that wasn't performed by us; it was performed by the health survey team.

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DR. BECKER: Budget and resources. We have field work which was 1.2 million Euro. The chemical analysis was 2 million Euro. And what we count in numbers is the management evaluation levels performed at our agency. It was design, supervision, development of hypotheses, scientific publication and so on, which was all performed by our staff.

Next, please.

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DR. BECKER: The objectives are comparable data -- on reference data. We want to identify exposure

pathways. And we want to find the link between the children's environment and children's health.

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DR. BECKER: To fulfill this we used several different evaluation steps. The first step is to describe that. And we do this -- can you click -- oh, it doesn't work -- by describing statistical data and by describing different subgroups of the population like you do in NHANES also.

Exposure pathway we do multi-variate statistical evaluations to find these pathways and to define political or health measures against the exposure. We have this example of 1 hydroxypyrene in urine. You have creatinine that's important for the level in urine. We have age. We have grilled food consumption. We have East and West Germany. Higher when it is in East Germany. We have ETS exposure at home. And we have exposure to traffic and chocolate consumption as an example.

(Laughter.)

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DR. BECKER: Links between environment and health. As I said, we are still evaluated these topics. We are fully aware that the cross-section study is not the ideal instrument to do these evaluations. But we thought that the prevalence of these health issues might be big

enough to do the evaluations. And it came out that, for example, the allergic sensitization against indoor specific mold spores was not seen often enough in all population. So we may change this to embedded few controlled study -- case controlled studies. Sorry.

We want to analyze irritation of the eyes and the respiratory system due to formaldehyde and VOC, and allergies due to nickel and chromium or scent and the noise of hearing and stress.

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DR. BECKER: Now I turn it to Marike.

DR. KOLOSSA-GEHRING: Well, thank you for inviting us.

Well, I will come to a choice of chemicals. And I want to present you some data which might show why we choose these chemicals and what it's good to use them for.

So this first slide was not copied from our Canadian colleague. But the general criteria we also use are of course the toxicological properties of concern and focus on long term toxic effects and the potential influence on children's health, the relevance for environmental policy, a widespread exposure of the general population. And to find out if this is the case, we have also some hot spot studies in Germany or we can use the German specimen bank to get an impression if we really

have a problem which is spread all over Germany.

Well, and then we want to know if we have a reliable sampling procedure and if analytical methods are available. Well, and of course the customers are also affected in or excludes chemicals from our survey.

But especially the existence of analytical methods is one very restricting point. I will come back later to this.

When we made our first proposal for selection of pollutants, we discussed reselection of expert groups and Scientific Advisory Board. And we tried to include as much external scientific knowledge as we could.

And the next, please.

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DR. KOLOSSA-GEHRING: And what resulted was the selection of chemicals. So we looked at a number of metals, at organochlorine compounds, at six PCB congeners, at pyrethroid metabolites, and six organophosphate metabolites. And they represent about 50 organophosphates which can be used or can be in products you can buy and use in Germany.

We looked at five different phthalates, measuring their metabolites. And there's one small mistake. The last phthalate is benzophthalate. DBzP would be correct.

Then we analyzed a number of PAH metabolites.

Not mentioned is our last trial to include also metabolites from oxidative metabolism of PAHs, which might give a better impression of the carcinogenic potential of the exposure.

Well, then we included biocides, PCBs and other chlorphenols.

Bisphenol A also met with great discussion and concern in Germany.

Nicotine and cotinine to evaluate exposure to an ETS. Well, and then some IgEs for mold fungis and stress hormones.

Next, please.

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DR. KOLOSSA-GEHRING: An example of lead from GerES I to GerES IV, you'd see a clear decrease in exposure levels in adults as well as in children. A situation of children in Germany has improved very much. It's comparable to the situation in Sweden. We don't have those very high exposure levels over about 100 microgram per liter of blood, which can be observed in other parts of the world.

However, lead is still a chemical of interest, because newest research on carcinogenic properties and neurotoxic effects show that it's not possible to find a threshold level. And so we do not want to take lead from

the agenda even if the political measures we took, which was ban lead from in gasoline and replacement of the majority of water pipes, were successful. But we still have children with about -- with higher levels of lead in those areas where the drinking water pipes have not been exchanged yet. However, we do not have a relation between lead in drinking water and HBM values in children, because the number of children which have those comparatively higher levels have gonorrhea.

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DR. KOLOSSA-GEHRING: DDE. Now I will present two examples for persistent chemicals: DDE, metabolite of DDT, has a chronic toxicity. And it might be carcinogenic in humans. And It was banned in West Germany in 1972. And in East Germany it was heavily restricted at the beginning of the 70s. However, it was banned in East Germany with a reunification.

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DR. KOLOSSA-GEHRING: And so we investigated only children which were banned years -- decades after the ban on this persistent chemical. And when you look at the exposure levels in Germany compared to the U.S., you see that even if the levels have decreased, we have a much higher exposure in East Germany still in adults as well as in children as compared to West Germany.

And so the levels are in both parts of Germany higher than they are in the U.S. And so it's still a chemical of concern, especially when we see from our data that the average exposure level has decreased by 50 percent in the last -- during the last 20 years. But we have still some groups of children, for example, very slim children coming from West -- from East Germany which have a fourfold higher exposure than the average. And also for the toxicological assessment of these data, this might be of importance that only calculating with the average goes too short.

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DR. KOLOSSA-GEHRING: We have an influence of the socioeconomic situation of the children on their PCB levels. Socioeconomic status was defined in our study according to education of the parents, job of the parents, and the family income. And you can see for DDT, measured as DDE, and the sum of the PCBs, a clear influence of socioeconomic status on exposure level. In this case the children with a high socioeconomic status show the highest exposure levels for other chemicals or other environmental factors. It's true that the children coming from families with a low socioeconomic status, we have a high exposure.

But these findings were very important for us, because the tendency to focus interest on children with a

low socioeconomic status has to be questioned because obviously, especially concerning the exposure to biosites, we need much more information contained in education of higher -- of persons with the highest socioeconomic status and we need different measures and also target-specific designed for people with a low socioeconomic status. So it's very important not to focus only on the one part of the population but to make the right decisions and complaints for the different parts of the population.

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DR. KOLOSSA-GEHRING: I want to go on with the PCBs. Also chronic toxic chemicals also banned in Germany -- in the whole of Germany with the reunification. They were used much more in West Germany compared to East Germany.

Next, please.

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DR. KOLOSSA-GEHRING: So we again have the different distribution with a higher exposure in West Germany.

And here you can see a clear influence of the age of mother at the birth of her child -- of her first child on the exposure level of the children to PCB.

For DDT, we only see an influence if we add up the mothers older than 30 years. But that's not

significant. Relation might be due to the fact that women in East Germany are still used to get their children much earlier than in West Germany. Most of them before they're 25th birthday in Germany. They're a little older. And so for the West Germany typical PCB exposure we see a high influence on exposure levels from the age of the mother.

And this might be very interesting, because we are especially interested in Germany and persistent in bio-accumulating chemicals during the last years. And DDT as well as PCB are used as model substances to get an impression of what those persistent bio-accumulating chemicals might do which are still unused. And I will give you some examples for that later.

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DR. KOLOSSA-GEHRING: Phthalates, they're also mentioned. And the phthalates -- we had a surprise when we evaluated the pilot phase data from the phthalates. They are found in -- they are ubiquitously found. They are used in a broad range of consumer products and toys. And toys, they are now restricted in the European community.

However, we find phthalates in every child we examine. They have chronic toxicity due to the endocrine and reprotoxic properties.

And we have the restriction only for some

applications now.

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DR. KOLOSSA-GEHRING: Here you can see some data from the German specimen bank, which allows us to see what industry has done during the last 20 years of an intense discussion on phthalate toxicity. The most well known and established phthalates were DnPB and DEHP. The brown and the blue line indicate the use of these phthalates from 1988 to 2003. And you have the mean concentration giving on a logarithmic scale. This might irritate you.

(Laughter.)

DR. KOLOSSA-GEHRING: But we have a decrease of the use of these phthalates by about 40 to 50 percent. And as far as we know up to now, the use of these problematic phthalates is still on a comparable level. But at the time we are working on most recent data.

And when these two phthalates decreased, other phthalates and chemicals to replace them increased in their use and we find increased exposure levels in the population.

And these data lead us to the conclusion that public regulators should think about more measures than voluntary agreements, and some restrictions for some applications, because we do not see the decrease we want

to see from a point of public health support.

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DR. KOLOSSA-GEHRING: We evaluted the data for this model. You can see the relative cumulative frequency and the estimated daily uptake for DEHP in this case.

You see that we found this chemical in all children we investigated. And we recalculated from the metabolites we found in urine how much DDHP was taken up by the children per day. We had to use toxicokinetic data for this. And we compared this daily uptake with existing values for acceptable daily intake. And unfortunately ADE or TDI values were derived by a number of different scientific groups and committees. And in this light you see lines -- the dotted lines that indicate the reference doses or TDIs from different organizations like U.S. EPA, the European Risk Assessment for Children -- or for Adults. And dependent on which TDI you used, you find a different number of children exceeding the acceptable daily intake. It was a clear indication for us that children in Germany take up too much phthalates with a problematic toxicological property.

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DR. KOLOSSA-GEHRING: So we did this first calculation in our group together with our cooperation partners from universities. And we are also supported by

a Human Biomonitoring Commission, our agency, which consists of established experts in the field of human biomonitoring in Germany. And they derived a set of assessment data -- or assessment "values" is the better word, I think -- one of which is the HBM value, human biomonitoring value. And this value is derived on the basis of toxicological and epidemiological data, and gives an indication which concentration in the child can be supposed as uncritical. And if the exposure level exceeds the value of HBM Value 1, we think it's a reason for concern and a reason to look for the sources and for further research.

Well, and if possible this commission also derives HBM Value 2, which is thought to give the clear -- a clear indication of a real existing health concern.

Our Human Biomonitoring Commission derived HBM 1 value for phthalates for DEHP. In this case it's given as a sum of the two main metabolites of DEHP. And here you can see the values for those five children exceeding the acceptable daily intake from our pilot study.

Two of the children exceed this value only in a small amount. But there's one child where we can see an eightfold higher concentration when acceptable.

And this was a reason for us to focus more and extend our activities in the evaluation and measurement of

phthalates in the population in Germany.

Next, please.

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DR. KOLOSSA-GEHRING: The derivation of the human biomonitoring value, well, here are some more details. We have ADI or TDI values ranging from 4 to 66 micrograms per kilogram body weight a day. We have no effect levels differing for a factor of 10. We have them derived during 1994 and 2005, which might reflect the development of toxicological knowledge during this time.

The Human Biomonitoring Commission decided to use the study of Wolfe and Layton as the key study, with a NOAEL of about 5 milligrams per kilogram. Well, I mean these phases they derived differentiated HBM values for children, women of child-bearing age. And the rest of the population, which reflects the different sensitivity of those different parts of the population to the effects of phthalates.

So I think most of you know that exposing adults to phthalates will not show the slightest effect. But if you expose a child into a home or during the early development, you see the effect especially on hormone production in the testis.

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DR. KOLOSSA-GEHRING: And I mentioned already the

human biomonitoring values, which were derived by our commission. And they derive human biomonitoring values only for chemicals without carcinogenic properties, which limits the number of HBM values that we have.

And I explained already before that HBM 1 value gives an indication from which exposure level there's a reason for further research and looking for the sources in the fetal exposure. And HBM 2 value gets a limit for health impact. All these data are based on human data up to now, because that also restricts the number of HBM values the Commission can derive.

We now try to extend our concept and include also, except for the daily intakes, the first example. So that was DEHP. And I have not brought up some data on other phthalates with me, but it might be interesting for you that in the case of Butyl -- of dibutyl phthalate, we have the exceedance of acceptable daily intake by nearly 40 percent of the children. And all these exposures are assessed only for single chemical assessment. And we wonder if it's wise to stick to the single chemical assessment, because we have a number of chemicals, the phthalates or also the organophosphates where we have exposure to a number of chemicals working on the same mechanism and effecting the same endpoint.

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DR. KOLOSSA-GEHRING: So if you want to know more about the GerESes I to IV and the pilot study, you can visit us on our website, www.umweltbundesamt.de/survey-e. We have -- can you go back?

So you see on the right-hand side the data for the studies on adults as well as on children, the publications. You find all information on the human biomonitoring we did in these, especially in GerES IV, and the most latest publications also on this Internet site. And the main information are in German and in English, so you only have to click on the bottom for English.

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DR. KOLOSSA-GEHRING: Chemicals which are not included up till now in our activities but are of high interest for us are persistent in accumulating chemicals. In the European Commission we have a new chemical legislation which is called REACH - Registration, Evaluation, and Authorization of Chemicals. And in the preparation of this new chemicals regulation, the European Commission made up a number of working groups in which chemicals of concerns are discussed, because the majority of industrial chemicals will still be only tested with a very basic set of data. But chemicals of concern will be viewed to a process of authorization and intense testing.

For the PBT substances it's not quite clear what

will happen. And therefore the working group on these persistent chemicals listed up about 120 persistent chemicals which are still in use. And producers had the chance to supply information showing that these chemicals are not toxic or not of concern anyhow.

Some of these 120 chemicals persist in organisms but do not fulfill the test criteria for PBT or vPvB substances. And at the end of the process about 50 persistent at accumulating chemicals remained.

I presented the data of the PBCs and DE to you because they give us an impression what these 50 chemicals might do also in humans. Up to now we have not evaluated those latest PBT substances. And that was due to the fact that there are no analytical measure -- methods to measure them in HBM.

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DR. KOLOSSA-GEHRING: Here you see four chemicals from this list. Two of them are still on the list. Two others persist in organisms that do not fulfill the test criteria. And we asked the contractor to develop HBM methods for us, because as a next step we want to look for these four chemicals in samples from specimen bank. As Kerstin mentioned already earlier, those are samples from students. And if we find them in those students, we are thinking about the target population in which we should

look for them before we do a full assessment.

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DR. KOLOSSA-GEHRING: And now I want to focus my view on activities in Europe.

Here's the second small mistake on our slides, because Germany is not reunified on this slide.

(Laughter.)

DR. KOLOSSA-GEHRING: But fortunately it's not the case any longer.

But it gives perhaps an impression of the different exposures we have in East or West Germany. Because as an inheritage of the communistic regime in East Germany, they have still higher exposure levels 20 years after reunification, still even if during the last 20 years our government put a lot into this in reducing exposure levels by a number of additional measures to reduce exposure in East Germany.

But in Germany, we started activity in human biomonitoring because of the environment and health projects of the EU. And the European Commission is very interested in an all-European human biomonitoring project, which is unfortunately difficult because many of these countries do not have human biomonitoring at all or only on a very small level. And where some studies had been conducted, they were made with different chemicals;

different methods; different objectives; different population samples, study designs, questionnaires. And so we end up with a lot of data which are not comparable and very insufficient knowledge.

So Germany is the only country in which the population representative -- a human biomonitoring study has been done up till now. And in the European Commission we decided to make up a working group to share our knowledge and to think how we can establish a first steps towards European biomonitoring.

Go to the next slide, please.

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DR. KOLOSSA-GEHRING: Due to the very large differences in knowledge, experience, and money available, we decided to make a basic scenario. And all member countries want to take part in the pilot study, which was developed in the project, which was supported by the European Commission. ESBIO stands for Expert Team to Support Biomonitoring in Europe. And 24 of the 27 European countries are interested and want to take part in the pilot study. All of them will have to analyze lead in blood, cadmium in urine, mercury in hair, and cotinine in urine.

And for those who have a more extended knowledge and experience and are more keen to go on scientific

questions, we developed a Scenario 2 as a shopping list. So all member countries can decide which part of Scenario 2 or which parts of Scenario 2 they want to do.

And this shopping list includes PAH, the phthalates, perfluorinated and polybrominated chemicals, flame retardants, organochlorines, organophosphates, and pyrethroids in urine.

And they're inspired by what we did in GerES. But they extended the program due to a mother and the children's program. But in the first round we only want to go on a very small number of samples, because from the process of ESBIO we already learned that there are a lot of technical and organizational problems which we will have to face.

Next, please.

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DR. KOLOSSA-GEHRING: The results of ESBIO can also be found on an Internet side, which will follow the results of this preparation of the pilot phase where a proposal for the objectives for an EU-wide human biomonitoring touring approach.

And also a justification for the recommended priorities, because a priority-setting was very important in this very unhomogeneous group of European member states.

A proposal for pollutants and biomarkers, including a justification of recommendations. And to be honest, I don't think that this selection of -- will be helpful for your Californian projects, because we have to integrate the east European countries, which are focusing -- or some of them are focusing -- or facing real toxicological problems in the environment due to their unextended protection at the workplace and they're not very caring a way to use chemicals in the environment.

So it's more a look back to what the undeveloped programs did from ten years ago.

You also find in the basic documents a protocol for population sampling recruitment and biological monitoring, questionnaires for the pilot project, and the protocol for a harmonized way of collection and analyzing selected premiums and for data management. We also there saw that there are very large differences in the ideas how to handle all these issues.

We in Germany with the GerESes have about 2,000 information per child. It's from all the different parts of our project, which Kerstin mentioned earlier.

I think in this exercise we will have to handle a much smaller number of information per participant. But, however, it will be a task to handle it.

Next.

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DR. KOLOSSA-GEHRING: This is the website where you can find information on the ESBIO project and the plan to a pilot study: www.eu-humanbiomonitoring.org. This is in English, and so you will not have a difficulty to get the information.

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DR. KOLOSSA-GEHRING: I want to thank you for your attention. And a special thanks to our team members: Andre Conrad, Andreas Hunken, Margarete Seiwert, and Christine Schulz, which you might know from publications. And if you are not visiting us on our website, I hope you will find publications from these authors, which can contribute to your considerations for your projects.

Thank you.

(Applause.)

REPRODUCTIVE AND CANCER HAZARD ASSESSMENT BRANCH CHIEF ZEISE: Thank you.

So do we have questions?

Tom, did you have your hand raised?

PANEL MEMBER McKONE: No. I've been looking for a microphone.

Thank you. Sort of an interesting presentation. Thank you for coming all the way over. I've been to Germany many times. It's a long flight. I'm sure it

works the other way.

Actually it's more comments. There's a couple of things that struck me as you were going through this, and I think we should bring out to consider. I mean I think it's very interesting that in the U.S. and Canada there's no concurrent monitoring of the ambient or the household environment, then in Germany and Europe there is concurrent monitoring, right, of the household environment of the subjects that are in the biomonitoring program. I think that adds a dimension that's quite interesting.

But the other point is in a lot of your discussions showing trends, like phthalates going down or you may be seeing flame retardants going down, it brings up an important issue in selecting chemicals; that is, that a lot of chemicals serve a function that must be served. And if they disappear, something else is going to come in their place. And one of the things I think we have to think about is not to just focus on chemicals that are disappearing and say that's good news without asking what's taking over that function.

For example, if as the brominated flame retardants start going down, you have to ask what's taking their place. Well, right now at least in consumer products we're seeing a huge rise in organophosphate flame retardants. Because the computer is the things we use --

still have to meet the flammability test.

Similarly, with phthalates dropping, there's a lot of effort to get them out, what's taking their place. Again, in some cases it's siloxanes. But I notice you have siloxanes on your list.

So, again, I think one of the things to think about is not only what we want to trace historically but a vision of what chemicals serve what function, so as they disappear we know we're looking for their substitute right away and not sort of thinking everything is fine because our chemical concern is disappearing.

DR. KOLOSSA-GEHRING: Well, this is -- I tried to show this dilemma with the persistent chemicals. Because two of the four we are going to investigate, over which we are developing analytical methods, are used for the applications in which PCBs were used up till now. And of course if we do not have an analytical measure -- analytical methods to measure them in HBM and if we do not have a proper toxicological risk assessment, we are in a dilemma.

But one consequence of our study is also to make recommendations for reduction of exposure in the households, because we realize especially when analyzing about 70 VOCs in indoor air that the chemicals we bring into our houses and into indoor air will be present in

indoor air afterwards. And so we recommend persons to use their water, to use household products, to restrict use of a thousand plastic articles, which -- well, are not really necessary -- if they wish to reduce the exposure of themselves and their children.

DR. CLARK: Yes. I'm Dr. Henry Clark, West County Toxics Coalition, again.

Thanks for the presentation. Actually I visited Germany myself also. Nice place in Frankfurt.

You mentioned a point there I wasn't quite clear on. You said that -- I don't know if it was -- I think it may be in the phthalates maybe. But this is to refresh your memory. You indicated that they were -- the chemical was taken out of some products but remained in others. And I don't know -- you didn't give no explanation as to why that was the case.

The other concern is that whereas in Germany and the European Union, you've added certain chemicals in products. But is this just for the European Union, or are companies able to produce a product with those chemicals and, say, ship them to other countries like Africa or India or somewhere else that doesn't have the strict controls that generally the European Union has.

And the last question is what the gentleman asked here, is that -- you know, we take certain chemicals that

we are perceive as dangerous off the market and out of products, and then we put other chemicals in there to serve the same purpose. Well, the question is is that those alternatives that we put in, are they any safer? Or do we go down the road until the children and the people get sick and die from those and then we start studying those? Or is there any studies upfront before we start using something else as a substitute?

DR. KOLOSSA-GEHRING: Well, thank you for your questions.

Yes. I mean I think the benefit from the European activities for other countries is that products produced in Germany or the European Commission underlie a strict restriction. And so I mean it's set standards. If German or European products are exported, they have to fulfill the European standards.

And, additionally, if we talk about release of chemicals from products, this changes the discussion not only in Europe but also the discussion of our cooperation partners in France and the world.

The replacement of chemicals is of course a problem. And our agency works with a lot of voluntary agreements with the industry.

When we both think chemicals should not be released from products, we sometimes find agreements

that -- for example, mask fragrances will not be used any longer in household products or products for personal hygiene.

But there are some cases where agreements do not suffice and where we have to make a binding regulation. And this is increasingly difficult in the context of the European Commission because of the enlargement to this 27 member countries.

But I think that is one part of our task, to look for proper risk assessment for replacing chemicals. But as indicated by the phthalate data from the specimen bank, even 20 years of very controversial and intense discussion about toxic effects of phthalates, they are not reduced voluntarily by that extent that we have to face.

And so I think scientists and regulators from the governments really have a task to put some more energy or to support the energy put in this issue by industry produce as well. And also by users, because we found out that the users support with their personal behavior, also their exposure levels. It's not only government. It's also the responsibility of every person.

REPRODUCTIVE AND CANCER HAZARD ASSESSMENT BRANCH CHIEF ZEISE: Gina.

PANEL MEMBER SOLOMON: My question is about the VOCs, because I notice that you made the decision to do

indoor air monitoring for the VOCs but not to biomonitor for those chemicals. And I was hoping that you could explain a little bit more about why you decided not to biomonitor for the VOCs and what considerations went into those. Because, as you know, CDC is biomonitoring for them, Canada is not, Europe's not, and Germany is not. So it's an interesting question.

DR. BECKER: Yeah. And the simple reason is that for a lot of VOC we measure in indoor air. We don't have analytical methods for HBM. And the other simple question is money. So that's it.

DR. KOLOSSA-GEHRING: And also for some of those -- but we found it out at the end of the study -- that for a number of you cease the concentrations in indoor air have decreased so far that it would be difficult to measure them.

So for the well known VOCs of concern, we have -- we could reach some success. And so it was more easy to do it in indoor air.

REPRODUCTIVE AND CANCER HAZARD ASSESSMENT BRANCH CHIEF ZEISE: So then Mike and -- then I saw a hand over here. Was it George?

PANEL MEMBER WILSON: Thank you.

You mentioned the REACH. And I'm interested in the REACH registration process that is expected to capture

to some degree persistent bio-accumulative toxic substances and vPvB's, very persistent very bio-accumulative substances, if they're imported or used more than one ton per year. And my question is, if you're -- two questions. One is if your program is monitoring that process for identifying a candidate chemical for biomonitoring?

And second, I think more importantly, is if you think the criteria that has been set under REACH are sufficiently sensitive to capture chemicals of concern for biomonitoring?

DR. KOLOSSA-GEHRING: Well, my personal feeling is that they are not sufficient. And that's why human biomonitoring programs will get much more important than they have been in the past. Under REACH, there is one way to measure them. Success of risk assessment by industry is observation of exposure trends. And from our perspective, human biomonitoring will -- the measure in question to control how proper industry conducts their risk assessments. But unfortunately that means we have to develop a lot of analytical methods for HBM. And the assessment which has to be done for chemicals is not very extended. And, unfortunately, they also restricted the number of animal experience, so we have this -- it's so difficult to interpret in future data.

And we also have the task to improve our models for especially bioaccumulation and persistency, because the P force at P4, they were very excellent an example where chemicals do not fit into the criteria we regularly use for definition of persistency, but they are persisting. And that is why we feel that our information on the -- on PCBs and DDT, which are banned for many decades, are still very important because in this case as we see the number of chemicals and fits to what they promise. But also we get an idea that we have to be very, very careful when we release chemicals which persist to the environment, because we can not get rid of them again even if we bend them in all applications once.

REPRODUCTIVE AND CANCER HAZARD ASSESSMENT BRANCH CHIEF ZEISE: George.

DEPUTY DIRECTOR ALEXEEFF: Yeah, thank you for your presentation.

I have maybe a technical question. But it has to do with when you were comparing slides 29 and 30 and 31 and 32, when you were comparing the health levels with the biological sample levels. And in the first one, in 29, you were looking at what we call a reference dose, and you're comparing the exposure to the reference dose.

And then in other ones you developed a new value -- HBM value, an HBM 1 and an HBM 2. So it looks to

me like the HBM 1 is very similar to reference dose, no adverse effect level, consider uncertainty factors, come up with some level. And I'm just wondering if you felt there's a need to have like an HBM type of level as opposed to somehow just back-calculating to a reference dose. Or does the HBM value have some other sort of regulatory impact?

DR. KOLOSSA-GEHRING: Well, it was a new way which we went when we calculated this when compared to the acceptable daily intakes. And that wasn't one can say a technical way to handle the issue, which we choose in our working group with our partners.

There had been new risk assessment for DEHP most recently. And therefore a number of European countries, for example, UK, do not wish to reconsider phthalates. And when we did our first assessments, we realized that this might come to a critical point. And therefore we asked the Human Biomonitoring Commission to discuss the issue, because we didn't want to open up that question alone and we wanted to have the input from experts.

They came on a different way but using the same data to comparable results as we did.

Well, at this HBM values, as well as the only statistically derived reference values, which we derived from the GerESes, are established methods in Germany to

judge if chemicals are critical or if an exposure is critical in an individual case or for the general population. So it's our well established instrument which has kind of a reliability in the regulators and in the scientists and in general.

REPRODUCTIVE AND CANCER HAZARD ASSESSMENT BRANCH CHIEF ZEISE: Dr. Moreno.

CHAIRPERSON MORENO: Yes, thank you.

I was wondering if maybe you might be able to make a few comments about some of the differences between the two programs that we've heard today. In the Canadian Health Survey, we have the biomonitoring survey and some examination of the participants.

And in the Environmental German Survey we have the biomonitoring in the survey but ambient measurements. And I was wondering if, while we have you both here today, you could talk a little bit about the differences and what are the benefits of either one. Because they're a little different.

DR. KOLOSSA-GEHRING: Our combination of health survey, environmental survey, human biomonitoring, and ambient monitoring is to look for the sources. And so for some chemicals we can see how large or if there's a contribution of one external source to human exposure levels at all. And that makes it more easy to derive

recommendations for the government and also for the general population.

DR. BECKER: May I add something.

Especially in the house dust, we included for children because we saw the K children play on the ground, you know, the hand-to-mouth behavior, and how that should be an important exposure source especially for children.

It came -- then we analyzed house dust and we took the dust bags that's available in the household and we could not find very convincing correlations between the exposure in the dust and the exposure of the children.

So that does not seem so easy as it looks in the first place.

DR. KOLOSSA-GEHRING: We have a measure for exposure of indoor environment to chemicals we import into the indoor environment. And it's interesting to see how you retain this use of some chemicals is reflected by the levels of these chemicals in house dust or also in the indoor air.

REPRODUCTIVE AND CANCER HAZARD ASSESSMENT BRANCH CHIEF ZEISE: Thank you.

The last question. Michael.

CDPH EXPOSURE ASSESSMENT SECTION CHIEF LIPSETT:

Yeah, you had indicated that the costs for this program are just a fraction, in fact, an order of

magnitude lower, at least the numerical costs that you listed then for the other two programs.

Do you have any sense of what the costs that the staff time or the numbers of staff involved in these different government agencies in administering the program is? Because presumably that's the bulk of the cost.

DR. BECKER: During the field work and the evaluation phase, you can say we were fully employed scientists and, let's say, four or five technical staff members. And so you can calculate the cost maybe.

CDPH EXPOSURE ASSESSMENT SECTION CHIEF LIPSETT:

Okay. I was thinking also in terms of like the design supervision, sample management --

DR. BECKER: Yeah, we did everything --

CDPH EXPOSURE ASSESSMENT SECTION CHIEF LIPSETT:

You did all that?

DR. BECKER: Yes, um-hmm.

DR. KOLOSSA-GEHRING: But the expert or the external quality control or the scientific board, they worked just for free. And I mean scientists are very cheap in Germany, so we --

(Laughter.)

DR. KOLOSSA-GEHRING: -- well, some recommendations and supervision just for free. And I mean I think also there's the salaries for scientists decreased

drastically in Germany during the last three years. So it was not really expensive.

REPRODUCTIVE AND CANCER HAZARD ASSESSMENT BRANCH CHIEF ZEISE: Well, thank you.

I'd like to thank all our speakers today and this morning. And we'll be coming back in an hour to have some more discussion focusing on some of the chemical selection issues.

So if you'd please come back by a quarter of two.

I apologize for running late. But I think this was a most interesting session, so I thank everyone.

(Thereupon a lunch break was taken.)

AFTERNOON SESSION

CDPH EXPOSURE ASSESSMENT SECTION CHIEF LIPSETT:

I'd like to get started now. We're a little bit behind schedule for now. But we're planning to have this discussion go from now till about 3:15 or 3:20.

And before starting I just wanted to make a few minor announcements.

First is that tomorrow we have a full panel meeting, not here. The Scientific Guidance Panel will be meeting downstairs in the auditorium. And for people who work in this building, does that mean that people need to go through metal or not?

It does. Okay.

So it's starting tomorrow morning at 9 o'clock. And the main focus of the Panel meeting tomorrow will be on chemical selection as well. And that's going to be a more formal, on-the-record type of meeting.

Second, if people have not signed the sign-up sheets outside and you would like to do so, it would be good for the transcriber in particular to have the spellings of your names. But obviously this is something that's discretionary. If you don't want to, you don't have to do so.

The third, for people who have name tags, if you're coming to the meeting tomorrow, you can hold on to

them. If you're not, please dump them off in the box there so they can be recycled.

And then, fourthly, this afternoon I thought that we could focus primarily on interactions between the Panel and our distinguished speakers here to take advantage of the fact that our speakers are here only really for today. And so I'd like to focus specifically on the issues that the Panel has to deal with tomorrow and in upcoming meetings having to do with chemical selection.

So for other individuals from either staff or from the public who want to make comments, if the comments could be really focused on trying to -- is that my mike?

Sorry. Just back off, okay.

(Laughter.)

All right. Is this better?

I'm sorry.

-- that if the comments could be focused on the specific topic of chemical selection for the biomonitoring program for which the Panel has a responsibility of recommending to the program, then we would greatly appreciate that.

So having said all of that, are there any questions from members of the Panel for those speakers having to do with sort of overarching or cross-program types of issues that you think would be useful for you in

your deliberations about chemical selection?

Julia.

And could you use the microphone, please.

PANEL MEMBER QUINT: I don't know if this will come out in an articulate manner or not. But one of the things I think is really important especially for a first-time program, like the one in California, is to in the process of chemical selection, which I think many of the speakers said it's not a scientifically-based process but it's sort of art and science mixed together, is to try to think about choosing chemicals for which there can be -- I mean lead is a great example of a -- for a chemical that's a great choice, because you can actually see progress or see, you know, something happen as a result of your actions. You know, it's taking biomonitoring and moving it straight into some sort of, you know, action or policy decisions or whatever.

And I know that -- I guess my question is, in considering I think one of the -- I think it was the presentation from Germany where environmental policy was one of the considerations or criteria -- I don't know which of the presentations had environmental policy as one of the criteria by which you selected chemicals. And I would like to hear a little bit more about that. I mean, you know, we're faced with -- you know, a lot of you have

chemicals that have been around a long time, we've had laws, you want to see if they were effective, PCBs, you know, the pesticides, that sort of thing.

But we're also faced in California with a number of new chemicals that have been -- you know, are in commerce because of eliminating chemicals that have harmed the environment -- methylene chloride -- you know, we have a number of chemicals like that. We're getting rick of Perc in dry cleaning fairly soon, and it's being substituted by other chemicals.

You know, this is not very articulate. But how do you grapple with this thing of creating a balance between looking at progress based on old, you know, policies or things, regulations that you put in place versus trying to think in a forward manner toward, you know, new chemicals that are coming on to market to replace older chemicals? How do you factor in environmental policy changes as one of the criteria for chemical selection?

Did that make any sense at all? Do you actually think that way when you're trying to select chemicals? How do you get the biggest bang for the buck is what I'm, you know, putting in a very crude manner. Because you want this program to have an effect and you want to also demonstrate that, you know, if you do biomonitoring, that

some changes are going to happen, which is what this is all about, I think. So how do you handle those discussions? How do you factor that into your decision making?

DR. BECKER: Well, I can try to start to answer it.

PANEL MEMBER QUINT: It would be a miracle if you could.

(Laughter.)

DR. BECKER: And I think -- I personally think if you want to implement political measures, you need the sources and you need to expose your pathway. For example, we took our -- and store up the viewing samples and measured the phthalates. But we didn't have -- get at the suitable information about phthalate exposure in the questionnaires, because we did the analysis afterwards.

And so, okay, we find -- we can show now that there is -- that children take in too much phthalates, but we can't show exposure pathways as good as we would like to have to.

So we know maybe it's convenient foods were stored in volumes and those things. But we didn't ask it in the exact way to find the exposure pathway. So we can't translate it into any measures, and that's a problem.

And another example is acrolein -- that's the heavy metal. We analyzed it and we could show that from the dental amalgams children had much higher exposure than adults. And so this was -- this we could translate in political measures because amalgam fillings are no longer allowed for children in Germany.

So that's not an example where we could translate it and put it into another -- it depends on -- okay, that's my statement. You need to know exposure pathways.

PANEL MEMBER QUINT: Exactly. I notice in your presentation that you really made -- I thought it -- I was very impressed.

CDPH EXPOSURE ASSESSMENT SECTION CHIEF LIPSETT:

Julia, I'm sorry. Could you use the microphone so that -- it's going to be recorded -- for the transcriber.

PANEL MEMBER QUINT: That was a very good answer, because I did notice that you very much mentioned -- you've mentioned and highlighted the fact of exposure pathways being important or the knowing exposure pathways so that you can link them to some sort of intervention measures was important. And I think that that's -- thanks.

CDPH EXPOSURE ASSESSMENT SECTION CHIEF LIPSETT:

Did any other Panel members want to respond?

MR. HAINES: No, I just -- sorry -- I just had another comment.

Before we often put a substance on a large scale national survey, there's probably some need to do some pilot surveys and studies and so on to identify -- to actually measure them, their methods are there to measure them and so on. So that by the time you get to a national survey you have a pretty good idea of what -- if you can -- you know, it's feasible to do that.

The other aspect too, certainly in Canada, the process of doing the chemical risk assessment itself may point out to where the exposure sources are or where the gaps are and what they don't know as well, and can give you some indication of whether something is worthwhile measuring in a survey or pilot study and so on.

So it's not all just plunk into a national survey or not. There's other things that can be done.

Also -- and I mentioned this morning -- certainly in Canada, the third stream, which was on one of my earlier slides, it talked about the supporting biomonitoring research. And that's where some of those things can be addressed to help identify whether things could be measured or not.

DR. KOLOSSA-GEHRING: And we included some chemicals where we wanted to control if the political

measures were successful or which extend that were successful. We found out that in some cases the existing binding regulation was not fulfilled to the extent that should have been reached.

And where the new chemicals of concern we have also shared approach. We test interesting new chemicals and some from the specimen bank or from other smaller and not so expensive studies.

But what we have not solved technically yet is how we can get the inventory of the exposure of the person. Because if we only look for selected chemicals, we are always in danger to oversee high sources of exposure which we do not find by accident or by modeling or by theoretical considerations. And I think this is something we should develop and we plan a project where we want to look if we can get inventory of the chemicals and then identify where we have high peaks. But I think it's music of the future.

DR. OSTERLOH: One other accessory remark.

Sometimes policy pushes the science and sometimes the science pushes the policy. In our original survey we weren't planning on measuring mercury in children. And EPA was very concerned about mercury, both in children and women of maternal age. And up until just this last survey period, that's all we measured it in; and we measured it

in those two populations because EPA asked us. And then they actually paid NHANES to collect the sample -- additional sample volume just to do that.

And so now that we have information on mercury in those two groups, we're going back and we're now surveying the rest of the population and adding that. So we started out with a very small portion of the population to answer EPA's call for doing that.

Also, I think in comment to what Doug Haines just said, we're trying now in all of our future analytes that come up or rise to the surface of our attention, if we can develop a method, we're going to always survey what we call surplus samples to see whether we get any detection or not. Otherwise we don't want to throw them into this large recurring cycle of analysis that we do.

CDPH EXPOSURE ASSESSMENT SECTION CHIEF LIPSETT:

Thank you.

Okay. I think Gina had her hand up first before.

PANEL MEMBER SOLOMON: All right. My initial question was sort of answered. But now I have others.

Actually one was sort of minor. But with the ban on mercury and dental amalgam, I was just wondering if concentrations of Bisphenol A and that population group are going up, because that's what's used in epoxy resin fillings.

But, anyway, I actually was curious about some sets of chemicals that I guess could classify as emerging. The siloxanes came up in previous discussion. And clearly the German program, you're at least looking at one siloxane. I was curious whether CDC is looking at siloxanes at all and considering adding any to the NHANES program.

There have been regulatory efforts in Europe around the PBDEs. And there was also some discussion -- I think Tom McKone brought up the question of what's replacing those as flame retardants. So I'd be curious if you're tracking the replacements for the PBDEs in Europe and what you're planning to do there in terms of potential to include those chemicals in biomonitoring.

DR. KOLOSSA-GEHRING: Well then, siloxanes, it's a first step. We are still developing the methods to analyze them. And we didn't find in our literature viewing existing methods, with blood, for example. There are some with fatty tissue. But that's not to get with an uninvasive method, and so it wasn't acceptable for us.

With the PBDEs, we are conducting a project with a specimen bank where we trace a number of PBDEs in environmental species and in human blood. And this is a -- it's been so far an interesting project, because industry -- our producers measure with the same methods as

we use, which are established for the specimen bank and in samples. And we do the same measurements in some more extended samples. And this will be the first case where we exercise the REACH, how good control and assessment by industry are and if we find the same results. It's a kind of link test we do with each other.

The substances used for the replacement are not in our program yet, because we are still busy to look where we find these chemicals in the environment and if we come to the same results.

DR. OSTERLOH: On the PBDEs, that I'll enter into our 03-04 survey, which would be coming out later in this year. The PBDEs actually are followed by one of the folks who measured them in Sweden. He's running our laboratory on that and has followed that whole issue from the Swedish point of view in terms of the rising and then the falling levels in Sweden after they got rid of many of the PBDEs.

We don't right now measure the deca-PBDE, which is the one that is sort of replacing the penta- and the octa- or the tetra-ped to octa-PBDEs, which were mostly used in this country and were not used in Europe. And the phaseout of those started at the end of 2004. So our 03-04 data is enough to capture the prior exposure. And what we're hoping is with 03-04, then 05-06 and 07-08, we might be able to look at declines in the penta-, and

Octa-PBDEs, and then hopefully we'll be able to see I think by 05-06 the deca-.

Oh, one other little conversation. Some of the silicon-base siloxy compounds that have been proposed we're starting to look at. But we don't really have methods for it at this time. Another compound that's sort of on the horizon is 1,4 dioxane, which is used in a lot of cosmetics. And we suspect that because that's so, that there's probably human exposure. And we'll probably be analyzing some samples with a partially developed method in the near future.

DR. BECKER: Can I -- because it's something I want to answer this Bisphenol in the teeth. I mean this is the point that shows that these big surveys are somehow inflexible, because when we implement the GerES IV with the children, it was I mean 2000 or so. This Bisphenol in our case was not on the agenda. So we don't have a question about dental fillings resin.

So what I want to say, and you have to be -- the aim of the survey must be very clear. Do you want to produce reference variables? Then you make your survey and that's it. Then you can count and translate it into concrete political measures. Do you make reference for this? That's a value as such, of course. But if you have the intention to do -- to implement political measure, you

need more information, not only reference values. And that's it.

DR. KOLOSSA-GEHRING: And the too Bisphenol A we found in 89 percent of the children. But also from different sources, we guess. And we are still evaluating this data. So later.

DR. CLARK: I can't --

CDPH EXPOSURE ASSESSMENT SECTION CHIEF LIPSETT:

Okay. Let me -- I just wonder -- what I said at the beginning. We wanted to have it focused primarily for the Panel, but that there will be time for members of the public and for staff to ask questions as well.

But it's initially want to be to maximize the time that the Panel has for these people who come from faraway.

DR. CLARK: That's fine. Be clear where we comment. I have quite a few questions to ask.

Okay. All right.

CDPH EXPOSURE ASSESSMENT SECTION CHIEF LIPSETT:

Okay.

PANEL MEMBER LUDERER: Is this on? Can you hear me?

I have a question that relates to something that sounds like is very -- kind of a concrete part of the program that you described in Germany but that the other

two programs have kind of alluded to also, and this idea of having a biospecimen bank that then can be used to basically kind of do pilot surveys to look whether something that you're thinking about measuring is actually going to be likely to be found, maybe invalidating new assay methods for new chemicals that you're looking to measure. And so I was wondering if maybe you could talk a little bit more about, you know, how was that actually set up? Where do those specimens come from? Because I got the impression from the German program they're not necessarily old specimens from previous dura surveys but they're from some other source. And if you could maybe talk about that and the utility of that a little bit. And maybe the other people could address it as well.

DR. KOLOSSA-GEHRING: So the specimen is the second large instrument we use in our agency. It was founded in the beginning of the eighties too as the surveys, as the GerESes. It consists of 12 environmental species from the different levels of the tropical levels. So we have consumers -- well, some leave some predative X, and so we can follow up the nutrition line in animals and plant kingdom. And we also have human samples. So we can get a -- and also some sediments and soils. So we get an impression about the distribution of chemicals in the environment and in humans.

The humans, which our samples are medical students, aged 20 to 29, in four locations, one in north, one in south, one in east, one in West Germany. They are not representative. But we have samples -- 120 samples from each location every year. We have sufficient amount of blood and urine where we use comparatively small questionnaires to get an impression whom we are sampling. And these samples are stored in liquid nitrogen, so we have an archive to go back. For example, when we realized that phthalates are a larger problem than we thought some years ago, over the first P4 or the PBDEs or so, and we can go back and look when they increased and if they do decrease sometime.

And the latest development was to unite these both two instruments in our section. And so we are -- we will go to optimize the cooperation, because up till now we had the benefits theoretically but it could have been better organized. And now all the persistent chemicals, so it's -- a hint of some problems we had.

And we have the opportunity, if concern about a chemical or a group of chemicals raises, to look if they had -- can be found in environmental species or in humans. And when we want to assess if a chemical is of a large concern, then we go back to these samples; because while we have a large amount of samples available, it's no

problem to spend them.

But of course we have a number of criteria, because we want to use them for important purpose and not just for measuring metals which we can measure more easily in another context. And with these analytical methods we are developing for the persistent chemicals, we found a contractor who develops the methods for the four chemicals, when we will test them in the specimen bank samples, and then decide how to go on.

Another alternative could be to sample from the general population a small amount of samples to look if we -- if these newly developed methods can be applied or if we need to do more research on metabolism and kinetics of the chemicals. But it's always a great effort to get samples from about 150 people or so to get a reliable view on exposure. And so it's better to use specimen bank samples.

CDPH EXPOSURE ASSESSMENT SECTION CHIEF LIPSETT: Mike.

PANEL MEMBER WILSON: Thank you for that.

And I just want to get back to this question that I had earlier for John around how we rationalize the chemical selection process. And each of your presentations sort of alluded to this sort of unscientific process that you had to go through in determining what

substances were going to be included in the biomonitoring program. And, you know, I worry about that because we may be looking at substances that may or may not be of priority for public health. And one of the reasons I raise that is in looking at the pesticide use reporting information for California, we have this very unique program that gives us information on use, on distribution and dispersions of pesticides in the state. And all of the high production volume -- pesticides that are released in high volume in the state, with the exception of one or two, do not appear on the CDC biomonitoring list. So here we have good information on the likelihood of exposure, but it does not appear on at least the federal list.

And so my question is: If we had that kind of -- if we put that information to use in California on the pesticide side of things, or ag side, is that a reasonable, rational approach to identifying chemicals of concern for biomonitoring? And should we apply that same model of chemical, introduce and dispersion, on the industrial chemical side as well?

DR. OSTERLOH: Well, I think you've summed up where we've come from in terms of our history. And I think in my talk I was trying to give other suggestions on where one could come from. And those use reports and, as you said, use and dispersion, I think are one of the

better places to get that kind of information. And at least you have a standardized way of approaching the topic. There are other ways that things percolate to the surface. And a lot of times it's just in the news media, it's in science publications, and things like that. And you can pick or choose those, because scientists within your office think that they're important. But it isn't a balanced approach, it isn't one that, you know, picks amongst all of the possible candidates.

So I think -- we're finding, for instance, some new pesticides -- well, pesticides that have been coming out for almost 30 years, a group called the substituted urea herbicides -- are used along roadsides and other places. And we were anticipating that surely we'd find a lot of that. And I think our next report is going to show some detection but not as much as we thought.

I think if we had really a lot better data on use of those and then were people possibly exposed to those kinds of chemicals, we might have had a better handle up front on those different types of herbicides. The number of those are myriad. I was surprised myself when we were just learning about them how many there were. And yet each one is using small quantities and usually not in too many public places. So maybe that explains why we're unlikely to detect it.

So I think in terms of looking prospectively, having something that you can come to grips with about use, about production, about dispersion is one of the best ways to go.

CDPH EXPOSURE ASSESSMENT SECTION CHIEF LIPSETT: Okay. Julia.

No, it's not Julia.

PANEL MEMBER BRADMAN: This is just stepping back to an earlier question.

John, is there any consideration in CDC to move some of the sampling down to children under 6 years old, 0 to 6?

And then related to that question -- I know in Germany you mentioned you were doing children down to 3 years. You talked about getting two or three mils of blood from children. And have you -- in your programs have you had different priorities, different actual -- ideas depending on your subjects? Have you tried to maintain that standardized across your entire group? I remember in the Canadian group you actually had different targets depending on age group. I wondered if Germany has done that. And then again to have CDC consider extending the age range.

DR. OSTERLOH: We get asked that question a lot. And we do consider it quite a bit. And, in fact, we do

measure in whole blood down to one year of age for blood lead, blood cadmium, and blood mercury. And that's in part because those three methods are now combined into one sample that only takes a few drops of blood that you can get from a heel stick. So there are technological limitations with regard to sample size.

There are other concerns when you get younger age for urine and trying to collect an uncontaminated specimen. And while that doesn't prohibit us necessarily from doing it, we do have concerns about collecting uncontaminated specimens. We're working at least for some of the urinary metabolites that we think -- for instance, phthalates and some of the pesticides, we're moving in that direction to try to at least go a little lower.

We want to analytically -- NHANES would like to. But I think because of what they do within their trailers and things, they have limitations.

So I think in the near future we're likely to get down to some earlier age, but I'm not sure exactly what I can tell you as to the answer to that right now.

MR. HAINES: We haven't decided what we're measuring in kids yet. But there are some practical limitations that we're going to have to be looking into, how much blood can you take from a child? And I think five mils is not unreasonable. Or you could probably take

less for lead, cadmium, mercury, and some of your basic trace metals.

But as far as we can also collect urine from younger children is not as straightforward in a national survey. Although there are methods such as potty inserts or diaper inserts as well. But how feasible is that, you know, in a national survey? So we'll have to try to figure that out. And there are some practical limitations that have to be considered when we develop these kinds of surveys.

DR. BECKER: You asked about priorities of all substances. And of course we have priorities with the urine sampling. The first priority was that we wanted to compare our data with our -- so the first priority were for the samples from the pollutants that we have had analyzed before.

To the blood thing I want to say that at least in Germany taking blood samples from children is a question of ethics. So we were not -- not allowed to take blood samples of higher volume from the smaller children. We would have liked to do, because for most of the sample substances, for example, for -- the why components the concentrations are higher in the -- the concentrations increase with decreasing age. So the younger children had the highest values. So, yeah.

CDPH EXPOSURE ASSESSMENT SECTION CHIEF LIPSETT: Okay. Julia, did you want to ask your question?

PANEL MEMBER QUINT: Yeah, I just wanted to find out how -- what rationale CDC used for choosing VOCs that are being added. Was there -- I mean how did you select those particular VOCs?

DR. OSTERLOH: Many of them were on different agency priority lists. The other part of it was technical in that we could measure 33 different VOCs in a small blood sample using the technology that we're using.

I thought your question was going to be: Why did we go to blood? I think that that would have been a harder question to answer.

PANEL MEMBER QUINT: Well, I'll ask that too.

(Laughter.)

DR. OSTERLOH: The answer will be is that after we're done with the blood, we'll have a much better perspective on blood than we will actually have on all of the urinary metabolites that have ever been done. But we have really very limited other studies that we can compare to. Some of the earliest -- I'm going in and out of -- some of the earlier studies actually did some blood specimens many years ago by different technologies, and they were limited in their sensitivity.

But we're probably going to stick with blood just

because we can get so much bang for the buck with it.

CDPH EXPOSURE ASSESSMENT SECTION CHIEF LIPSETT:

Other questions from the Panel?

Gina.

PANEL MEMBER SOLOMON: This is actually for some of the California lab folks, a follow-up on Ulricke's question about the specimen bank.

I'm just wondering if you could describe some of the bank specimens that are available at the DTSC lab and DPH labs

CDPH ENVIRONMENTAL HEALTH LABORATORY BRANCH CHIEF FLESSEL: Well, I can tell you there are no specimens that -- in Department of Public Health --

CDPH EXPOSURE ASSESSMENT SECTION CHIEF LIPSETT:

Peter, Can you use the microphone.

CDPH ENVIRONMENTAL HEALTH LABORATORY BRANCH CHIEF FLESSEL: Yes. As far as the Public Health lab, there are no specimens available.

DTSC ENVIRONMENTAL CHEMISTRY BRANCH CHIEF PETREAS: In what sense do you mean available?

Myrto, please use the microphone.

In what sense to you mean available? I mean the problem has not started yet.

PANEL MEMBER SOLOMON: Well, my understanding is that, for example, you have frozen samples of specimens

from sea mammals and other -- you know, seals from the San Francisco Bay and so forth they've used in previous studies. And so those were potentially -- was one of the things that's sort of interesting about the specimen bank in Germany, is that it's not just human samples but that they're actually sort of looking at other biota to somehow inform decisions about what things to sample. And so I was sort of interested in hearing a little bit more about that.

DTSC ENVIRONMENTAL CHEMISTRY BRANCH CHIEF PETREAS: Well, we have specimens left over from previous studies - marine mammals and fish and bivalves. But humans to have blood and -- but, remember, these were selected, well, part of it, with a certain design. So they were selected from cancer patients and controls or from pregnant mothers. So that the collection and the samples we have represent the hypothesis of the study that gave us the samples. And I don't think we can -- maybe you could use the controls, and we have done that, at some point to see what would be the PBDEs or the PCBs in the controls. But that's not representative of much. I mean this is pretty limited.

DR. OSTERLOH: I wanted to add one comment. I don't know if I mentioned it earlier, because I was sort of speeding through the last part of my talk. But one of

the real limitations that we're running up against in NHANES is actually sample volumes now. And we're actually rearranging, you might say, our subsets. We take one-third subsets of the overall NHANES population, so that we can pair them such that they make sense. For instance, we're trying to get perchlorate and iodine in the same subset so that those can be looked at with respect to perchlorate's effect.

But we're also trying to do it so that we are conserving specimen. For the most part we can sometimes go back on specimens that we have and didn't use all of the specimen. NHANES sets aside a certain amount of specimen that individual investigators, including ourselves, petition for, that is, investigators outside of CDC as well as within CDC, petition to use. And that is usually there and does tend to get consumed.

Then there's sort of what we call surplus specimens where, if we're allotted 1 mil to measure something, say, 1 mil of serum, and we use a half an ml to do that and we have another half an ml for repeats, if we don't do that many repeats we basically have surplus specimen. And that's how we actually did the perchlorate initial analysis, because we were somewhat interested, as well as other agencies were being interested, in what perchlorate was. And in this case it was urine that was

the surplus specimen.

And so we went back and the analysis was done in the 2001-2002 database.

CDPH EXPOSURE ASSESSMENT SECTION CHIEF LIPSETT: Any other questions from the Panel?

MR. HAINES: Oh, I'm sorry. One more response.

CDPH EXPOSURE ASSESSMENT SECTION CHIEF LIPSETT: Go ahead.

MR. HAINES: For exploratory purposes, it's always possible to look at ways to pool biospecimens so they increase your volume to do some exploring of either new things or old things.

There's one study that's being done by one of the provincial governments in Canada where they have access to 30,000 stored biospecimens from across that province. And they're pooling it by age and gender and region. And so they've segmented them into these cells, and then doing measurements of quite a few things.

Now, they give you a point estimate, so they don't give you a good distribution. But it's one of the techniques that can be used to explore or to even come up with some population-based levels of different compounds.

CDPH EXPOSURE ASSESSMENT SECTION CHIEF LIPSETT: Dr. Culver.

Could you use the microphone, please.

PANEL MEMBER CULVER: One of the very big problems with epidemiologic studies -- hello.

Yes, okay.

One of the problems we all recognize in trying to do epidemiology is having real exposure information. The technique usually is to use surrogates of exposure, that farmers are exposed to insecticides, for example, and so forth and so on. I was wondering whether in the CDC data one can go back and select the data based on the information you have on population -- I mean occupation or on other aspects of exposure, so that the data can be more useful for epidemiology studies?

DR. OSTERLOH: Well, I kind of covered part of that earlier in that, you're correct, exposure data is very valuable and it helps us make correct exposure assignments with respect to doing future research or epidemiological studies.

Most -- I'm trying to think which part of the question did you want answered there?

PANEL MEMBER CULVER: Could I go into your dataset --

DR. OSTERLOH: Oh, yeah.

PANEL MEMBER CULVER: -- and find information about occupation?

DR. OSTERLOH: I'm sorry. Yeah, that kind of

followed the line of an earlier question in terms of looking at micro-populations or secular views of the data. And as I had iterated earlier, there's a confidentiality issue. There's an issue of nonrepresentativeness. But that there is a possibility, if you're interested in that and you think that there's enough information there, that you can go to the NHANES data center to pull down that information. They're hoping to expand that process in the future with all the restrictions and caveats that go with it.

Generally speaking, you know, if you're looking, say, at foundry workers or something within the NHANES population, there aren't going to be that many. If you're looking at people who could be described as blue collar workers broadly, there would be, you know, more. But with respect to specific occupational titles, it would be difficult to get a good handle on enough people.

PANEL MEMBER CULVER: My question -- I guess my question leads to, what should we do here in California in terms of collecting collateral information about the population that we're sampling? And how much detail should we go, for example, into population -- into occupation or into homemaker activities and things of that sort?

DR. OSTERLOH: Well, I think you always want more

is the answer.

Many people come back to the NHANES database and they look at it to determine -- to examine what the determinants of exposure are. And our breakdown in the report merely just breaks things down by race ethnicity, sex, and age, some of those encapsulating determinants of behaviors and things like that.

But you can go into the NHANES database and find out answers to questions like how many dimes a week did you exercise, how many times a week did you eat fish, how many times a week did you go see a doctor, and things like that.

So there are a number of behavioral-related pieces of that database that can be used to look at the associations between exposure and behaviors.

I'd guess I'd like to go back and make one other comment about how much sample we have. I forgot to mention -- and this is sort of advertising -- is that we're also putting out -- response to an earlier question -- we collect a lot of information on nutrition and -- or NHANES does, and then we're doing many nutritional markers. And so we're coming out with a report later this year on nutritional biomarkers which primarily relate to vitamins and vitamin metabolites, fat soluble, water soluble, iron indicators, things like that.

And we're hoping to expand that report in the future as well.

MR. HAINES: We have a fairly similar approach. We do collect ancillary information in a questionnaire in terms of sociodemographic characteristics as well as education of workforce activity income. There are other questions related to food consumption, pesticide use in homes, age of -- or how old the home is, and so on. What they can do is it can help you do some correlation analyses if you want.

If you're trying to look at -- the other thing I have to mention is that we're also asking for consent to link their Canadian Health Measures Survey data with their long-term health administrative databases, and we do that through that Statistics Canada, who has the share agreements with the provinces themselves. So it's a portal I guess into their long-term health used from the health care system of the individuals.

So you're able to do some analysis long term there which can help you -- which we expect can help us in the long term -- look at longer-term associations.

But a cross-sectional survey has one purpose and certain limitations. And if we're looking at trying to do more cause-effect type of investigations, we may need to look at different models of studies, and perhaps a

longitudinal study is more appropriate for that end.

We can still collect biomonitoring information to help us better characterize the exposures of those individuals. And that's where the strength of the biomonitoring comes in. But we still need to collect more ancillary information, and longitudinal study may actually be better to collect in some cases better data on sources exposure facing the facts.

CDPH EXPOSURE ASSESSMENT SECTION CHIEF LIPSETT: Dr. Denton.

DIRECTOR DENTON: Is this on?

I have a question for the Panel. And, that is, given the importance of resources, we are at this point in time going to be able to operate this program on a fraction of what CDC is investing and only a portion of what Canada is investing. And it sounds like Germany is able to do it pretty inexpensively, but you have a lot of structure there that is already set up. So if you had to look at your universe of chemicals that you've selected for biomonitoring, and you had to make some decisions based upon a cost, would you choose all of those categories of chemicals that you've chosen but only have fewer analytes? Or would you choose heavy metals at the expense of persistent organic pesticides? Or how would you -- how would you handle the situation that we have of

starting a program, of wanting it to be as useful as appropriate and as statistically representative of California, and yet having a limitation of resources?

DR. KOLOSSA-GEHRING: Well, the metals are nearly just for free. So it's very cheap to measure them. And so it was easy to decide to include them.

With the persistent chemicals, which are very interesting because they have such a long-term effect if they are effective, I think I would focus for the next survey on chemicals which can be found in a majority of persons. So we analyze some where only -- is comparatively small number of samples are above the limit of quantification. And that was something I would test out in advance before starting such a large survey.

And, additionally, I would not do again the measurements in dust. I mean it's not a human monitoring issue, only if you want to elucidate the sources. The dust measurements were expensive and did not -- well, it's something that's good to be done once but not every time. And with the already bent persistent chemicals like TDE and the PCBs, I think I would select one as an indicator for looking at this further development of exposure models, but not seven as we did in parallel, because the additional information is limited.

I think I would prefer to include some of the

emerging substances which can be found in more than 40 or 50 percent of the samples.

DR. OSTERLOH: Well, I can't tell you what to measure or not to measure. And I think again the structure that's forming here is that you have to find out within your state what's of concern to people who are going to give you their vote for particularly the chemicals. But you also have to -- going to find out what is actually here in California in terms os use.

I mentioned one cost-saving approach, and that was pooling, in that we can actually lower our detection limit, save on analyses, still get some median point estimates. And if you were looking at dioxins, that's what I would do.

On the other hand, if you're truly looking at cost benefit, you might say, okay, we know nationally what's happening with dioxin-like chemicals and all the congeners, and you might say, okay, that's less important maybe to know in particular about California, because California may look like the rest of the country in that regard unless you have some particular reason to think that it doesn't. So if that's the case, you wouldn't want to necessarily analyze dioxin-like chemicals because that's one of the most expensive chemicals. I think I was saying to Michael earlier that if you took dioxins alone

out, that's two and a half million right there for those analyses. It's a lot of money.

Some other chemicals that are difficult to analyze but might be higher on your agenda, you know, are the PBDEs. They still are very costly to measure but of greater interest.

A lot of people are -- on the other hand, for dioxins -- we have these discussions all the time internally -- you know, dioxins are going down. Should we continue to measure those? They're of an historical interest because they've had such a long and interesting tale. But on the other hand, people are starting to find interesting relationships the longer we study the dioxins, and they are getting more interesting.

So if you're looking at it from a science point of view, you might not want to be driven just by how interesting they are. But you have to understand whether or not -- I think California has exposures beyond or different than what the national data might show if you're just going by that list.

DR. KOLOSSA-GEHRING: I forgot to mention we did -- to reduce the cost was -- measure some chemicals only in subsamples. So we decided if it's necessary to on the whole sample or only in, for example, 600 of the 1,800. And that gave us still a good impression about the

distribution. I mean the pooling has the disadvantage that you don't get an idea if you have highly exposed groups. And our evaluations clearly showed that especially the youngest children and children independent from the immigrational status or the socioeconomic status have different exposure levels which might go up to a factor of 4. And I think for assessment that's an important factor, when you have twice as high concentrations in some parts of the population are fourfold.

DR. OSTERLOH: I had one other suggestion. I lost my train of thought while I was going from pooling.

There's another approach. And, that is, that some chemicals within groups of chemicals are good markers for the rest of the chemicals in that group, in that they're all fairly well correlated. So like if you take, for instance, the PAHs, 1 hydroypyrene, that metabolite in the urine, is a good marker for general exposure to PAHs. You don't -- you may not find it necessary to characterize everybody's individual PAH -- other PAH congeners. That would save you money within the analysis that you do for PAHs. And you could just focus on that as a marker within the state. And then if that turned out to be, you know, high, you might subdivide that and look at all of the individual PAHs; or if you found it low, maybe not even

continue to do it.

Similarly, for some of the PCBs there are representative PCB congeners that you can focus on. The problem is you're still doing the chromatography, but you're not paying for all of the individual internal standards and you're not doing all of the data analysis for them, so there is a cost savings there. But you still have to have the instrument.

DR. KOLOSSA-GEHRING: Well, they never had hydroxypyrene, and we have a different view. We now investigate also the tetrodes in the subsample, because we want to get more information on the health impact of PAH exposure. And that means on the carcinogenic potential, which is thought to be better to assess with the tetrodes than with the pyrenes.

MR. HAINES: It's difficult to advise about what would be a core set of measurements. But certainly for us some of the trace metals or heavy metals would be relatively core, in other words measured from cycle to cycle.

But once you add your basic core trace metals, the other ones don't cost all that much to add.

There's other techniques as well to help contain costs. You can look at -- if you really want population representative sampling, you may look at collapsing age

groups. They have less sample size needed for those measurements. In other words it comes down to being a subsample within those age groups.

And, you know, as some of the measurements that we're doing are 100 to 200 to 300 dollars an analysis, if you collapse that from 5,000 to 2,000, you save quite a bit of money. So there are different techniques such as that that can be used.

DR. BECKER: Just a short comment from my side.

In the environmental survey we choose some of the substances according to information we had from the environmental media. For example, in Germany uranium is a problem in drinking water. And so we knew this, and then we included uranium also in the survey, for example.

The same as with nickel. We knew nickel was very often found in drinking water. We included it into the survey. So this might be a way to do it. I don't know.

CDPH EXPOSURE ASSESSMENT SECTION CHIEF LIPSETT:

Dr. Moreno.

CHAIRPERSON MORENO: Yes. I'm just wondering if -- how closely the three programs -- and if you're trying to bring people into the sample group to give a representative collection of what participants that represent each of the three countries. And did at any time with the programs did you particularly go after a

particular subgroup that you had -- knew had a high exposure and make an exception to -- and knowing that wouldn't be representative of the United States or Canada, but, you know, you were so interested in it, you took advantage of this opportunity and said let's sample farmworkers or let's sample people in a particular industry?

MR. HAINES: Well, since we're in our first cycle, no, we didn't try to oversample -- identify groups to oversample. There may be opportunities in the future as we move ahead with the next cycles.

However, other parts of the program have focused on first nations groups as well as northern Inuit populations, which as I mentioned earlier were -- through some other targeted monitoring, showed that they were four to ten times -- five to ten times more exposed to pops and some mercury -- and some trace models, mercury especially.

So those efforts have been made in those other more targeted types of surveys that we don't follow throughout those.

But when certainly Canada is looking in the future, some of the other groups that we're looking at are new Canadians. And some of the work that we did in the Great Lakes and St. Lawrence region as a country back in the mid to late nineties and up to 2000 or so identified

certain Asian groups as having higher levels of mercury. And we suspect that that's because they eat large numbers of fish meals per year, up to 180, 200, 250 meals per year, which might be the source as well as the use of traditional medicines and so on.

Oh, we say suspect because we haven't gone back and retested those things. But the Canadian Health Measures survey may after a couple of cycles capture enough of that sample that we can at least do our secondary analysis and look at that over the long run.

DR. KOLOSSA-GEHRING: So we wanted to have a sample that's representative for children living in Germany. So we only oversampled children from East Germany a little to get a representative of a sample for East and for West because we still have differences in the exposure levels.

There were a number of other specific studies in Germany in which they focused on hot spots, for example, but that was not the objective of our study.

DR. OSTERLOH: Like the Canadian study, for the most part special subgroups haven't been sampled as a structure of NHANES itself. But we do participate in separate studies that look at special populations, including, for instance, as was mentioned, similar studies, well, were mentioned, by fish eaters in the Great

Lakes region, and certain communities in and around the southwest.

And one community that we had focused on that was quite a bit in the news a few years ago was Fallon, Nevada, where the community was known to be exposed to high arsenic levels in their water. But the reason for going in was actually because there was a cancer cluster. And so epidemiologically speaking we were investigating a cancer cluster. But in reality we were -- in the end we were getting regional representation of what arsenic and other metal levels were from that geological basin of water supply.

So sometimes things happen because we're doing an epidemiological study. Sometimes we do special studies to look at special populations. But within NHANES the oversampling that is done sometimes for special groups is rather broad. I mentioned earlier in response to a question from somebody about pregnancy and that in one of the future NHANES surveys they're oversampling pregnant women.

MR. HAINES: Just another comment. And it relates back to possibly some costs. The more questions you ask, you know, those are more subgroups that you're trying to focus on in either a state survey or national survey, the greater sample size you're going to need to

capture all those and to answer all those questions. So it becomes a push-pull between how much -- how many questions you want to answer, how much sample size and what level of cost versus what reality is in terms of what resources you have to address those questions.

So you may not be able to hit all your particular subgroups first time around. You can look at cycling a question in, you know, in one cycle and oversampling the next cycle to answer different questions. But it becomes very difficult to answer all the questions in a one-shot survey.

CDPH EXPOSURE ASSESSMENT SECTION CHIEF LIPSETT:

All right. Could I get a sense of how many members of the public and staff want to ask questions?

Okay. We have three.

Okay. Dr. Clark, since you were asking before, do you want --

DR. CLARK: Well, I think LaDonna was before me.

CDPH EXPOSURE ASSESSMENT SECTION CHIEF LIPSETT:

Okay. Do you want to come up and use one of the microphones.

MS. WILLIAMS: I think she said ask the questions I asked in the morning in the afternoon. That ain't possible because I can't think of them. So I'm asking some new questions, listening to the Panel and the

questions that were raised.

One is: With CDC, is there really truly an effort to include environmental justice communities in these studies and the program? And one major thing that comes to mind to me is mercury. When you talk about the fillings in Germany, you know longer allow it to be used. In the United States, it is one of the only products available for low income families. You have no alternative.

So if Germany isn't using it and we know this is a toxic chemical of concern -- and I heard an earlier comment, if I'm not mistaken, from you that said mercury levels were lower. Am I correct? Your current data shows that the level of mercury is declining.

DR. OSTERLOH: No, we don't know that yet. We're looking to see whether -- we're looking to see whether it's declining.

MS. WILLIAMS: Okay. I thought you said that it was.

But in any event, I was wondering, to get some factual data, do you have plans on including low income dental patients, who have had to use this because they have no other alternative or no other means? That's one of the things.

The other thing that really concerns me, I think

of California's fish and mercury project, which we have all been a part of -- when I say "we," the EJ groups here in California, particularly here in the Bay Area -- we had to really push and force the issue for them to test fish that African Americans eat, in particular, catfish. When they first put together the fish contamination and consumption project, or fish and mercury, let me say that, they focused on fish that, they focused on fish that Asians and whites ate. And so as we move this project along here, it really, really concerns me in that once again African Americans are going to be left out of the priority pilot projects and the testing. And then I look at the chemicals that you have on this list and who chose them. It doesn't appear to me to reflect the communities that are sitting next to polluting companies and their chemicals of concern.

So I want to know what is really being done to address that. And it's not just up to the states because California's going to take its lead from you all. And as I said before, we dealt at the top of -- the head with Ms. Gerberding at the time. And when we raised the issue of environmental justice, we were basically pushed aside and the door shut. She said she wasn't that versed in it at that time when we attended the conference there in Atlanta and raised that issue. She pushed it aside.

I know you've dealt with Fallon. And Fallon from that community's perspective, you know, they're not primarily African American, but they were very dissatisfied with their interaction with you all.

So, again, I raise the question -- and I guess I can't remember it -- how do you plan on rebuilding that trust so that we can begin to trust the process and know once we get into this testing that we -- those of us that are exposed and have these exposures, if those are issues, can trust the process? Because right now, the way that it's set up, we don't. This process even here appears to be exclusionary in that the process is so interagency and so highly technical, it's like you don't really expect the average one of us to engage in this process. I can tell you, I, for one, I'm not here to be a fan or a bystander or a spectator. I plan on being involved in this process. And I am going to be demanding inclusion and accountability for the chemicals that have been allowed to contaminate me and my family and my community.

DR. OSTERLOH: Thank you.

CDC is definitely concerned about trust in everything that they do, and they try to be open and balanced and fair in approaching answers to questions that are before the nation.

The concern that you bring up about the -- what

we're talking here today about is national surveys, our survey being national and representative of the population, and it is that. There are -- the major ethnic groups are in that survey. That has been accomplished. We're at the forefront of developing this information in that we're only really seven years down the road in doing national biomonitoring. We've incorporated as much of a representative sample as is possible for the entire nation. Again, the picture of the nation.

In order to get to the smaller secular, special group kinds of questions that you're bringing up, we need to do special studies -- the cost question just came up -- about trying to include those within this larger study design. It basically isn't currently set up. As I think you heard when we first opened up, the National Health and Nutrition Examination Survey wasn't an environmental chemical survey at all and still primarily isn't. It's mostly about the health behaviors and nutritional factors in the nation as a whole.

So what we're adding are pieces to that. And I think it's important to hear what you have to say. I've heard this before in smaller presentations to smaller groups where they want their particular group or their particular issue represented.

If the survey could be designed or expanded to

encompass a whole bunch of smaller subset types of studies, that would be perhaps the way to go. But each question's going to be unique to that particular community or those particular exposures. And they might not be handled very well in the confines of a larger study.

Now, CDC does undertake many specific investigations. And I think you brought this up earlier in the morning. We will support investigations as long as our constituent states are in the lead to undertake those investigations. We well do the analysis. We're an analytical laboratory. And those laboratory tests can be supported if they're part of an investigation.

I'm not saying that -- you know, passing the buck back off to the state. But that's how we work on every epidemiological investigation. That's our charge. We work through the state public health programs.

So I think if this can be resurrected, your concerns, then we need to have -- after this meeting, if you'll talk to me and specifically give me some contact information, then I'll come back to the State of California and see what we can do.

Now, I'm in a particular area that just has to do with laboratory analyses. But we'll have to make it known to our epidemiological folks that there's a particular concern that you're interested in.

MS. WILLIAMS: Okay. So following along with that thought since you mentioned it, at this point it's a larger national type thing. Then can I ask you, within that scope, have you tested and considered low income dental patients who have only mercury as a choice to be put in their fillings?

DR. OSTERLOH: That would not be part of the study design, no.

MS. WILLIAMS: Okay. So can it be? Because we've got low income people all over the United States. And so that wouldn't be just a California issue. We can then be cost effective and hit everybody in all of these states. And the information is already available through MediCal. And I'm sure there's many providers. So that we can begin to use this as legislation to stop them from being able to put a contaminant in our mouth.

DR. OSTERLOH: Well, I answered no to your question about low income folks using dental amalgams. So it's not specifically a subgroup within the population. But low income populations are surveyed. They're part of the NHANES survey. Mercury is part of the survey.

The questions about dental amalgam use are part of the survey. And that information can be had. But with respect to the your question about communities and low income people and using dental amalgams, that would be a

focus study that's a separate question. But is that -- some of that data or parts of that data are available within the larger NHANES survey, yes. But it has to be ferreted out in terms of looking at those relationships.

DR. CLARK: Thank you. Dr. Henry Clark again, West County Toxics Coalition. I want to follow up on a couple of the concerns that LaDonna raised.

First of all, in regard to the mercury filling issue, I hear what you're saying and I hear LaDonna's concerns, and that is a concern of mine also. I don't know if in California or other places -- I had heard somewhere, and I don't know if it's true, that the mercury was not supposed to be used in the fillings anymore. Now, whether that's the case or not, I do not know. I've not heard of any health department or anyone doing any surveys to say conclusively that that is the case in California or anywhere else.

So in regard to that question, though, it's not only -- well, if you're outside -- well, in regard to that question, it not only relates to blacks or Afro-Americans or people of color. This relates to poor people, period, poor whites too. Because if they go -- if they're not on some -- medical insurance, if they go to the doctor and can't afford, you know, to pay, that they get the same

treatment as poor black people or poor Mexican, especially in the prison system where they don't have no choice. You've got blacks, whites, or whatever there. And they have no choice but take the medical treatment and the amalgam that's put in their mouth. They're like in the prisons, whether you're black, white, or whatever, you are going to get the same -- as far as I know, you get the same treatment. So the mercury's in your mouth.

So whether that's still current or not outside the prisons or inside the prisons, I don't know. It remains to be seen. But it's a big problem and it should be checked up on.

In the other concerns, you talk about specimen banks and so forth, you know. I wonder, what type of controls are placed on these specimen banks? You take the specimens or whatever, is it blood or whatever, you know, this is a highly controversial area, because what do you do with all that leftover? I mean you could take the stuff out, you can take that DNA stuff and go try to frame somebody or something. Have a Henry Clark working in some labor mine somewhere, and I don't even know about it. Because they didn't check my DNA or something in a crime or another vehicle. Because they'd never be like me, you know, because there is only one of me. Anyway, you get the point.

So all of these type of questions in terms of control, you know, and misuse, you and I really -- you may not think that this is important, especially an Afro-American. But when you start -- when you think about the syphilis study, I think that CDC was involved in that, where they let black men go with untreated syphilis, even up to recently, to test the effects of how untreated syphilis would have on a person's body. And they use black men as a guinea pig, and there was the whole conspiracy. Because when these people that were part of this experimental study would go to other doctors and so forth for treatment, well, they had a little list with their name on it. And these people did not know they were used as guinea pigs, they didn't know nothing about it. So we know that all of this nonsense happened.

Well, how are you going to control these specimens and so forth and convince people of color that this isn't another one of those same type of misuse and abuse type of things that we've become to be suspicious of in the first place?

The last question -- I believe the last one is this. I'm part of an advisory panel in Richmond there with the cleanup of Zeneca, which is a former chemical company. So I stopped off and talked to these people at the Department of Toxic Substances Control that we work

with there, especially Barbara Cook and Nancy Cook. And we are concerned -- we are trying to get some biomonitoring happening there at that site in Richmond because of the fact that the Department of Toxic Substances Control have -- and come up with findings as well as the community come up with findings that there is buried birds that's being found with dual organs, the organs are male and female, from contamination there at that particular site where no one knows what the nature of the contamination is and nothing. And not only that. But that site is going into the bay where people fish at.

So people are concerned not only about fishing and eating fish that's polluted from contaminated waters. But what of these chemicals at this site that's causing these birds, these life forms to have dual sexual organs and so forth.

So I talked to Barbara Cook about that. And we want to see if that site can be part of this biomonitoring process here, because it definitely needs to be looked into.

And so, here again, all of these questions. The gentleman raises his question I believe by stating that the study was basically a national study that he didn't -- it didn't focus on any particular I guess ethnic group that it sounded like is was a general -- well, you

know, that type of information is nonsense. That is not meaningful at all, because -- well, let me finish -- because it's not in the sense in terms of really getting down to, like they say, where a rubber meets the road in looking at who's really affected mostly; who's ignored; when the resources become available, who gets the resources to do anything, who don't. All of those questions.

Going back to the environmental justice question. It ain't no general -- it ain't no general nothing. Racism is alive and well in this country and in the world in terms of how we do -- allocated resources, health care, and any other thing in this society, period. And maybe a wake-up call to somebody who's in a state of denial. But let me tell you, racism is alive and well up to right now. Okay?

So the point is is this here. You just joined some of the general type of stuff. That doesn't tell me and Afro-American communities or Latinos nothing in terms of how we are directly affected in a disproportionate environmental racism or environmental injust way. You just lumped in to some overall summary that's going to hide the fact that it ain't just equal in trying to make it seem like that everybody is affected equally. If you don't separate it out and look at Afro-Americans or

Latinos or other people of color, you'll find that certain people are disproportionately impacted and it ain't no equal across the Board. And so when you do a study like you're talking about doing or some has been doing, it hides the fact that certain people in communities are disproportionately impacted and it ain't know equal playing field. And this is one of the problems that we are finding with the environmental justice field.

CDPH EXPOSURE ASSESSMENT SECTION CHIEF LIPSETT:

Dr. Clark --

DR. CLARK: That kind of a thing. This is a very important point, because this is one of the points that we are finding in our country, whether it's health and EPA or regulatory agencies, is that this whole new nonsense of trying to deny the fact of environmental racism exists and it don't refer to a race at all and just refers to a study or something, because we all people, we all human beings. Yeah, we all people, we all human beings. But the fact is that we ain't all treated fairly and that's what your study misses.

CDPH EXPOSURE ASSESSMENT SECTION CHIEF LIPSETT:

Okay. Just one comment related to specific community studies. The California program will be doing -- planning to do community studies sometime in the future. But the purpose of this particular meeting though

was to respond to a request from the Scientific Guidance Panel at its last meeting to look at what's been done in other programs to prioritize and choose chemicals for analysis.

And the issues that you raise, Dr. Clark, with respect to looking at specific communities, that will be part of this program at a later state. But at this point we're focusing on trying to develop the basis for selection of chemicals for this statewide survey.

With respect to one of the comments that Dr. Clark raised though about specimen banks, and could the German representatives -- did you want to respond to them in terms of the ethical controls that you have for how those things are used.

DR. KOLOSSA-GEHRING: Yeah, thank you.

Well, with the specimen bank as well as with the samples from the GerESes, we have to pass an ethical committee. And we are only allowed to take samples if the person agrees that we use the sample. And we also make a contract for which kind of purposes we can use the samples. So if we say we measure a number of chemicals, chemicals 1, 2, 3, 4, we are not allowed to add additional chemicals or use, for example, genetic information for something which is not contracted.

For the children, the ethical committee approved

if the individual child has a benefit from the study and they said, yes, the children have a benefit because we evaluated lead which might have an influence on the cognitive and neuro development.

So everything's very well controlled in Germany so the participants can be sure that their samples are not used for other purposes than stated.

And additionally I want to come back to the mercury issue. We found out that the amalgam fillings have only such a high influence in children compared to adults, so we do not have restrictions for the use of amalgams for dental fillings in adults. It's only a recommendation not to use them in younger children. And with this finding, also a campaign on oral hygiene was started, which linked -- led to the amazing success that during the last 15 years we have a drastic reduction of fillings in children at all. So today only 3 percent of the children have fillings. And some years ago it was about 50 percent or so.

So the combination of not using amalgams in children any longer and increasing their oral hygiene, they led to the success that the children are less exposed.

In adults, not the amalgams but fish consumption is the main influencing factor for mercury exposure.

CDPH EXPOSURE ASSESSMENT SECTION CHIEF LIPSETT:

Dr. Haines.

MR. HAINES: Are we staying on the same specimen question?

CDPH EXPOSURE ASSESSMENT SECTION CHIEF LIPSETT:

Sure, yeah.

MR. HAINES: I didn't have anything else to add on that.

In terms of biobanking, what we do in a Canadian Health Measures Survey is that we ask for consent for all components of the survey, including the physical measures, the lab reports or reportable diseases, biobanking and DNA storage. One thing I have to highlight is that we follow what we call a tri-council ethical guidelines. It's ethics policies in Canada which have been developed through our granting research councils.

For children, we obtain I guess their assent, if they're below 14, and a reconsent ones they reach the age of 14. So we have to go back and find them and ask a reconsent.

Our consent -- our use of the biospecimens are based on what they're specified at the consent stage. So we can't, willy-nilly, do things with the biospecimens. So they're really strictly, not I think say regulated, but controlled through our ethical reviews and boards.

In terms of mercury and dental amalgams, mercury amalgams are still used in Canada. However, this study will at least help us identify whether dental amalgams are a contributor to blood mercury or not, and will help us make some decisions in the future about the use of dental amalgams -- or mercury amalgams for dental fillings.

But there is a -- the dentists in Canada are -- many are switching to alternatives to mercury amalgams. However, they're faced with the ethical dilemma of whether the next thing that they're using, the epoxies and so on, are any better than what was used before, so replacing mercury with something else. And, you know, those are very practical issues, because what you put in your teeth has to last. So some really, you know, practical issues to consider there.

In terms of fish consumption, various provinces in the country issue fish consumption advisories in terms of the sports fish areas in the country. And that Health Canada also issues some specific market fish consumption guidelines for the protection of -- on the mercury side for the protection of women and younger children.

Also, in terms of a socioeconomic status, I have to admit that the environmental justice issues in Canada have not been as acute as they are in the U.S., from what I understand. So they haven't come out in the same way.

Nonetheless, the Canadian Health Measures Survey and the other surveys that we do study, they include socioeconomic status questions of race and ethnicity, so allow us to do some analyses and perhaps point where more attention needs to be given in the future.

CDPH EXPOSURE ASSESSMENT SECTION CHIEF LIPSETT:

All right. We're going to conclude at around 3:30. And I know Davis Baltz had a question that he wanted to ask. And so could we get Davis's question and response to that. And then, George --

DR. OSTERLOH: I just wanted to add something.

CDPH EXPOSURE ASSESSMENT SECTION CHIEF LIPSETT:

Actually, I'm --

DR. BECKER: One statement to the last question.

CDPH EXPOSURE ASSESSMENT SECTION CHIEF LIPSETT:

All right, Davis, one second.

Go ahead.

DR. OSTERLOH: I had one little piece of information.

I had answered the previous question by saying that low income populations are sampled within NHANES, and that's the case. There is a designation within NHANES called the poverty income ratio that's used to categorize the low income category. So that is actually there.

With respect to mercury, we speciate mercury.

And we know that in blood 90 percent of the mercury that's in blood is organic and it's mostly from fish sources. We don't know how much is actually due from the dental amalgams. But within the context of NHANES there's enough information to look at that information, because we look at where that mercury goes. It goes into the urine. And we can look at that as a function of dental amalgams.

I think that those were the three points I wanted to address regarding NHANES and mercury.

The other part of both the former two questions about race ethnicity, if you look at the contents of what was included in the folder, race ethnicity is broken down by Mexican-Americans, blacks and whites. And those categories you can look at -- for instance, with respect to mercury, there are findings that we do have in previous reports that show the differences between different race ethnicity groups. In terms of coming back to more secular studies, those are usually going to have to be done outside the design of the larger NHANES overall study design.

Thank you.

DR. BECKER: I want to say something to one issue that Mr. -- I don't know your name. I'm sorry.

MR. HAINES: Clark.

DR. BECKER: -- yeah, what he said.

What I want to say is we have in Europe a study in Belgium. And they left this concept to study cross-sectional. They analyzed different sites with different grade of contamination. And I don't know the California experience, but that might be something you should consider. I mean together samples in different areas with different contamination that you already are aware of.

CDPH EXPOSURE ASSESSMENT SECTION CHIEF LIPSETT:

Okay. Davis.

MR. BALTZ: All right. Thank you.

My name is Davis Baltz. I represent ??? Commonweal here in the San Francisco Bay area. We are interested to explore how biomonitoring data can help tell the story of how society use and regulate chemicals appropriately, and also how biomonitoring data can be used to develop policy interventions so it will protect the most vulnerable, especially children.

My question to you today since I don't think you'll be with us tomorrow is -- I was pleased to hear that Mr. Haines described in the Canadian program that participants who give biospecimen samples will be able to receive their results if they choose to with informed consent and so forth. Now, this a feature that is not available in the CDC program. But in California's program

the statute that's governing the development of the program is going to require that the state make this available -- some provision available to individual study contributors if they decide that they want to receive those results.

So I'd be curious to ask a couple of things: First, whether individuals who are tested in Germany get their results if they want them? And what the experience has been in Canada and what you anticipate in Canada for what percentage of people who give samples will actually want to know their results. What sorts of responses do you expect to receive, or have received in Germany's case, and what kind of follow-up do you do as the administrators of this program to answer people's concerns?

DR. BECKER: We report the results to the participants. We do this for those substances we can evaluate. That's what Marike says, because those substances we have human biomonitoring by this -- because we felt that if we tell them on a regular basis results that we can't evaluate and that they can't evaluate, that's not of -- that's not helpful.

In any case, if people are ask about the results, they'll get them. That's not an issue. But on the regular basis we tell those substances we can evaluate.

DR. KOLOSSA-GEHRING: And with one addition. So

in the case of GerES IV, we investigated children who actively participated in the study. And with the environmental tobacco smoke we had the problem that we had a level of cotinine in urine -- cotinine is a main metabolite -- which gives us the information that the child is an active smoker. And we ask the children and their parents is this child smoking or "are you smoking?" And we have the problem how to inform the child and the parents about the results without saying we are sure that your child lied when it said it's a nonsmoker.

(Laughter.)

DR. KOLOSSA-GEHRING: So then we try to find a diplomatic wording and said, "Well, this high of exposure level can be reached, for example, when..." And so just giving indirectly a hint without being, well, to offending to the children.

(Laughter.)

MR. HAINES: I have to differentiate between a couple of approaches. I talked about Canadian Health Measures Survey this morning and also alluded to the MIREC, Maternal-Infant Research on Environmental Chemicals, where in the Canadian Health Measures Survey we do provide the data or the results -- individual results if requested. And our Research Ethics Board, that's the way that they wanted to go. They approved that. However,

in the MIREC study, which dealt with another research ethics board, which was more clinically based, they decided that they would not provide, other than lead, cadmium, mercury, any of the results to the respondents. And so it's not necessarily completely in our control as federal investigators to do -- when we either partner with others to do this kind of work or whether it's wholly within the federal jurisdiction to do the work.

So it's not as straightforward as yes or no to provide information to the individuals. And the REVs really dictate -- or have a lot of influence. In fact, we can't go against the wishes on REV. Otherwise the project doesn't go forward.

DR. OSTERLOH: Just to correct the misperception. And the National Center for Health Statistics does report back results on folks with the same heavy metals that were mentioned if they exceed the known health thresholds, back to the participants themselves. But not the rest of the data, as you had indicated.

CDPH EXPOSURE ASSESSMENT SECTION CHIEF LIPSETT: Okay. I think --

DR. KOLOSSA-GEHRING: And what we additionally do -- one of the tasks of our agency is to counsel and inform the population about chemical exposure. So we always offer to answer individual questions. And we

supplied information where the practitioners specialized on environmental exposure can be found. So we help the participants to look for individual support in the region where they live, or they can ask us theoretical questions. We cannot answer individual health questions without seeing the people. So we had to split the opportunities to get information up.

CDPH EXPOSURE ASSESSMENT SECTION CHIEF LIPSETT:

Okay. Thank you.

This, I think, has been a very fruitful discussion this afternoon. And we're running a little bit late. But I wanted to ask George Alexeeff to present a conclusion for the agenda and adjourn the meeting.

DEPUTY DIRECTOR ALEXEEFF: First I'd like to thank the Panel members for being here, Dr. Osterloh and our CDC and Doug Haines from Health Canada, and also Dr. Becker and Dr. Kolossa from the German Environmental Hygiene Department. The information was very helpful and giving us a sense of other programs. We knew a lot about CDC. And now we know more about two more programs. It helps a lot. And think you for answering all the questions that were posed to you.

I also want to thank the moderators, Dr. Zeise and Dr. Lippset.

I want to thank the Panel members that were here

to be engaged in this, and also the members of the public that were listeners and also posed some important questions.

I thought I'd just mention a couple of nuggets that I got out of this, focused more on the chemical selection issue. There were a lot of other issues discussed as well. But I figured it's probably not good to mention those at this point.

One is I think to be really clear on the intent of the biomonitoring program. So if we're going to establish, for example, reference values, that might give us some issues. But if we really want to impact regulatory policy, then we need possibly to get other information at the same time, such as the type -- go either by questions on the questionnaire to make sure we have a good understanding of exposure or even considering additional exposure monitoring, to get a better sense of that.

Also, in terms of identifying candidates, we should consider as much as we can possible exposures that might be unique to California, such as using the pesticide use reports was mentioned. Also, some of the choices might depend upon technicological feasibility or agency priorities, which is one thing that we are looking into. Also, when we consider trends, we should also consider

trends of replacement chemicals if we're concerned about that.

One thing mentioned was that metals are very inexpensive to measure, so that should be done. Persistent chemicals, possibly just consider some particular chemicals as a signal for the other family of chemicals. And also look, if possible, to merging chemicals if they seem to be within the population.

Also consider subsampling to look at maybe some chemicals that might be of importance. And then also some markers such as 1-hydroxypyrene.

And then I guess the last point is to also consider, you know, in designing the program, concerns of impacted communities for the chemicals that might be of concern to those communities as well as any types of subsampling that might be available so that we could actually see what those communities -- impacted communities might be exposed to.

So those are my conclusions.

CDPH EXPOSURE ASSESSMENT SECTION CHIEF LIPSETT:

Okay. Well, thank you, George.

Now, I guess we are going to be adjourning the meeting now. And I'd like to just second George in thanking all of our distinguished visitors. This is really very helpful for the program.

(Applause.)

CDPH EXPOSURE ASSESSMENT SECTION CHIEF LIPSETT:

And in addition, I wanted to thank the Panel members for attending and all of the staff who worked so hard in making this come to a reality today.

I want to remind people again, tomorrow there is a the Panel meeting. We'll be in the auditorium starting at 9 o'clock.

With that, I think we'd like to adjourn.

Thank you.

(Thereupon the California Environmental Contamination Biomonitoring Program workshop adjourned at 3:41 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 workshop was reported in shorthand by me, James F. Peters, a Certified Shorthand Reporter of the State of California, and thereafter transcribed into typewriting.

I further certify that I am not of counsel or attorney for any of the parties to said workshop nor in any way interested in the outcome of said workshop.

IN WITNESS WHEREOF, I have hereunto set my hand this 23rd day of June, 2008.

JAMES F. PETERS, CSR, RPR
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