IMPLEMENTATION OF THE CALIFORNIA ENVIRONMENTAL CONTAMINANT BIOMONITORING PROGRAM: 2010-2012

Appendix E

Agenda and Summary of Findings from March 2011 Biomonitoring California Workshop on Understanding and Interpreting Biomonitoring Results

California Department of Public Health
in collaboration with
California Environmental Protection Agency's
Office of Environmental Health Hazard Assessment and
Department of Toxic Substances Control

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Biomonitoring California Workshop
Understanding and Interpreting Biomonitoring Results
Elihu M. Harris State Office Building, Auditorium
1515 Clay Street, Oakland, California
March 17, 2011, 9 am to 5 pm

9:00 Welcome
George Alexeeff, Acting Director, Office of Environmental Health Hazard Assessment

9:10 Overview of workshop goals and introduction of morning speakers

9:25 Biomonitoring of Exposure to Environmental Chemicals: Complexities in Interpreting Data *Dana Barr, Emory University*

9:55 "Is It Safe?": New Ethics for Reporting Personal Exposures to Environmental Chemicals
Ruthann Rudel, Silent Spring Institute

10:25 Break

10:45 Making Sense of Human Biomonitoring Data
Tina Bahadori, American Chemistry Council

11:15 Morning questions and discussion

11:45 Lunch

1:00 Introduction of afternoon speakers

1:10 Interpreting Biomonitoring Data in a Risk Assessment Context Using Biomonitoring Equivalents
Lesa Aylward, Summit Toxicology

1:40 Importance of Pharmacokinetics and Distributional Analysis for Understanding Biomonitoring Results
Dale Hattis, Clark University

2:10 Understanding and Interpreting Biomonitoring Results in the Context of Sustainable Communities
Amy Kyle, UC Berkeley

2:40 Break

3:00 Afternoon questions and discussion

3:30 Panel discussion (all speakers) with audience participation

4:45 Wrap up

5:00 Adjourn

For questions on the workshop, contact:
biomonitoring@oehha.ca.gov

Highlights of Discussion at the

March 17, 2011 Workshop on Understanding and Interpreting Biomonitoring Results

On March 17, 2011 Biomonitoring California held a public workshop in Oakland on "Understanding and Interpreting Biomonitoring Results." The objectives of the workshop were to:

- Discuss approaches for understanding and interpreting biomonitoring results, including strengths and weaknesses;
- Discuss methods for developing comparison levels in blood or urine;
- Discuss scientific challenges with interpreting biomonitoring results, including how to address multiple chemical exposures and sensitive sub-populations; and
- Provide guidance to Biomonitoring California on approaches for understanding and interpreting biomonitoring results.

The workshop included presentations and panel discussions by six national experts and interactive sessions with the audience. Workshop materials, including the agenda, the workshop description, the presentations, and the full transcript, are available online: http://www.oehha.ca.gov/multimedia/biomon/sgpwrkshp031711.html.

Highlights of Workshop Discussion

There was a rich discussion of many issues at the workshop, which is captured in the full transcript (http://www.oehha.ca.gov/multimedia/biomon/pdf/March172011Wrkshptranscript.pdf). Below are some highlights of the discussion, focused on issues most relevant to what the Program is currently working on and grouped into general topic areas. These points were drawn mainly from the discussion periods and reflect ideas from the speakers and members of the audience. They do not necessarily reflect the views of the Program.

Returning individual results: context and uncertainty

This section includes paraphrased comments from the speakers and audience related to returning results to individual participants and how to provide context for those results, especially in the face of uncertainty.

- Most people want to receive their results. The main questions that people want answers to when they get their results are: What did you find? How much? Is it high? Is it safe? Where did it come from? What should I do?

- The Program can use the consent process as a conversation, to let people know what to expect when they receive their individual results - i.e., that the Program will tell participants what is known, and that for many chemicals, the health implications are uncertain.

- Communicating uncertain science is challenging and it is important to find a balance between creating unnecessary worry and providing false reassurance.

- People are familiar with dealing with uncertainty and with decision-making in the face of uncertainty. We do it all the time in many contexts in our lives.
- Putting individual results in context with respect to study population values and NHANES or other relevant comparison populations is valuable.
- By including both the range of values observed in the study population as well as the 5th to 95th percentiles from the NHANES program, individuals could see whether the exposures occurring in the population the study they participated in are unusual.
- Using NHANES levels alone as a baseline for comparisons has some limitations because the demographics in California are different than those in the U.S. as a whole.
- Conveying the variability of measurements of the same chemical in the same person, especially for non-persistent compounds, is important and challenging.

Information on chemical health effects and exposure sources for report back *This section includes paraphrased comments from the speakers and audience related to providing information to participants on potential health effects and exposure sources of biomonitored chemicals.*

- If people are provided with information about exposure sources for a biomonitored chemical, some will be interested in deciding whether or not to use a particular product or participate in an activity that may lead to exposure. This may be true even in the absence of information describing possible health effects related to their biomonitoring results. By providing information on exposure sources and ways to reduce exposures, the Program can support this decision making.
- To provide for informed decision-making, it is important that that information about exposure sources be accurate. Commonly used sources of information, such as those on the Internet, can be inaccurate and out-dated.
- It would be helpful if consumer product manufacturers would provide more information on what chemicals are in their products.
- How much is known about a chemical's health effects and exposure can guide communication. When there is a good understanding of exposure sources and health effects, the message can involve a clear action message (e.g., lead, mercury). When there is some information about the health effects but very little about how to reduce exposure, precautionary action and more research (e.g., flame retardants) can be recommended.
- Describing the history of when a chemical was first introduced and how it is used is one way to provide context for understanding individual results. For example, if a population had been measured 20 or 30 years ago, the reference range for many chemicals would have been much different. Certain chemicals would not have been detected at all because they hadn't been synthesized yet.
- In explaining the presence of chemicals that have long been biomonitored (lead, dioxins, PCB compounds), the Program could include a description of these as success stories, in which biomonitoring data was used to spur actions which led to declining exposures to these chemicals.

Developing levels of health concern or other health comparison levels

This section includes paraphrased comments from the speakers and audience related to the possibility that the Program would develop health-based values to guide interpretation of individual participants' results.

- The Program can provide advice on follow up actions to participants where there is some certainty (e.g., lead, mercury). Follow up action on these well-known hazards is most simply guided by setting a specific level and talking with anyone who exceeds that level.

- An argument against setting a "bright line" level of health concern for most chemical exposures is that this approach does not account for an exposure that may shift the whole population lower on a distribution of a health outcome. For example, lead exposures can affect intelligence across the whole population by moving some of the population who are already on the lower end of the distribution into the "retarded" range, and some on the higher end out of the "gifted" range. It is not only those who are above a certain threshold level who are impacted by this overall shift in the distribution.

- Biomonitoring equivalents (BEs) are not intended for interpreting individual participants' results. They are most useful for population level interpretation of biomonitoring results. BEs are a translation of existing risk assessments, so are limited by the quality of those risk assessments.

- The Program should not spend time developing risk interpretations for individual participants for most biomonitored chemicals, as attempting to do so could delay progress of the Program.

Evaluating exposures and studying early effect markers

This section includes paraphrased comments from the speakers and audience related to-possible approaches for using biomonitoring studies to identify exposure sources and investigate early markers of possible health effects.

- Conducting follow-up with people who have exposures at the upper end of the distribution for the study population can help identify highly exposed populations ("Who's high and why?"), find undocumented exposure sources, and explain aspects of population exposure variability.

- The "exposome" attempts to conceptually incorporate many different factors that interplay to impact health, including stress, diet, exercise, as well as chemical exposures. It is limited by the data inputs, which may not include any info on exposures during sensitive time periods (e.g., puberty, infancy).

- Intervention studies are one way to identify exposure sources and can provide information about how people might reduce their exposures. Potential exposure sources are removed, with samples (e.g., blood or urine) taken before and after the removal. In some studies, potential sources may be re-introduced (e.g., known dietary sources of pesticide exposure) and samples taken again. These intervention studies may allow researchers to document and track changes in the levels of biomonitored chemicals attributed to the changes in exposure sources.

- Correlational studies analyzing which chemicals occur together in biomonitoring data can provide insights to sources of exposure. Such analyses might also point to new directions, in terms of health effects to look for that might be caused by those co-occurrences.

- It would be valuable to relate biomonitoring data to "natural integrator" outcomes like birth weight, which can be influenced by multiple chemical exposures as well as many other factors.

- Biomonitoring studies can be an opportunity to look for early effect markers (e.g., thyroid hormone levels), which could be done most efficiently by focusing on people who have high exposures to particular compounds. One way to do this would be to use an `omics' approach to evaluate hundreds or thousands of chemicals in samples collected over time, measure markers, such as changes in enzyme levels or protein production, and observe how changes in exposure sources affect these early markers.

Aspects of biomonitoring measurements
This section includes paraphrased comments from the speakers and audience related to analytical and measurement issues that could impact interpretation of results.

- The level of detection (LOD) is not a static number, but can change over time, as well as for different runs of the same machine testing samples for the same chemical.

- Methodology improvements that have led to very low LODs for some chemicals but not others mean simple "detection" of a chemical as a signal of interest is problematic. Detection is very much driven by our analytical capabilities.

- The Program should consider taking multiple measurements in each person in a study rather than having a larger total study size with only one data point per person. This would provide a better estimate of the variability of levels seen in an individual, especially for non-persistent chemicals.

Informing public health and regulatory actions
This section includes paraphrased comments from the speakers and audience related to using biomonitoring results to help guide Program priorities and public health and regulatory policies.

- Biomonitoring California was created partly to address a strong interest of certain subpopulations (for example, communities living in highly industrialized areas) to gain information that would help them to understand what they perceive as their increased risks

from chemical exposures. For the Program to be able to give subpopulations that kind of information, it needs data that could establish baseline exposures for the general population of California.

- The Program should focus on generating biomonitoring data that can be used to set population-based priorities and inform policies on which chemical exposures warrant action.

- The desire to look at emerging chemicals was an important driver in the Program's beginning. That effort should not be slowed down in any way, for example, because of a need to figure out a context for communicating the results before the Program studies emerging chemicals.

- For the Program as a whole, it is important to think strategically about the questions that can be answered with the kind of results that will be generated, and how these questions relate to the responsibilities of Cal/EPA and CDPH.

- The legislative provision to return results to participants was about people having a right to know, and was not intended to be a primary goal of the Program.

- Learning about biomonitoring results can lead to an increase in environmental health literacy. Information gives a person or a community the power to make choices, including individual and policy level actions that could reduce exposures.

- Both manufacturers and people who use products tend to reduce use of the substance or product that is identified as posing exposure or health concerns. The pattern is that well-studied chemicals tend to get replaced with alternative substances that are typically less well studied than the substances that are being replaced. This issue is an ongoing challenge.

- The design of chemistries for consumer products should take into account biopersistence and other characteristics that lead to chemicals being human health concerns. Design characteristics that make a chemical commercially valuable (e.g., really stable, flame retardant) may often be the exact same properties that make them undesirable for the environment and human health.

Next Steps

The Scientific Guidance Panel (SGP) for Biomonitoring California will discuss the March 17 workshop at their meeting on July 14, 2011 in Sacramento (for meeting details visit: http://www.oehha.ca.gov/multimedia/biomon/07142011agenda.html). The Panel will provide their comments and recommendations on topics related to the workshop.