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

Report to the California Legislature

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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Table of Contents

Executive Summary **5**

I. Introduction and Background **9**
- A. Introduction 9
- B. Background 10

II. Program Structure and Resources **11**
- A. Program Structure 11
- B. Program Resources 13

III. Scientific Guidance Panel and Chemical Selection **14**
- A. Scientific Guidance Panel Meetings 14
- B. Chemical Selection 16

IV. Biomonitoring California Study and Sample Design **18**
- A. Community Studies 18
- B. Results Communication 20
- C. Methods to Approximate a Statewide Survey 22

V. Biomonitoring California Laboratory Status **23**
- A. Laboratory Organization 23
- B. Instrumentation 23
- C. Quality Assurance 24
- D. Laboratory Information Management System (LIMS) 24
- E. Current Chemical Testing Methods 25
- F. CDC Site Visit 26
- G. Analyses of Archived Biospecimens 27

VI. Public Participation Activities **27**

VII. Conclusions and Recommendations **29**

APPENDICES **31**
- A. Health and Safety Code (Division 8, Part 5, Chapter 8, Section 105440, et seq. (SB1379))
- B. List of SGP members and short biographies
- C. Summaries of recommendations made by panel members at recent SGP meetings
- D. Biomonitoring California's lists of designated and priority chemicals for biomonitoring
- E. Agenda and Summary of Findings from March 2011 Biomonitoring California Workshop on Understanding and Interpreting Biomonitoring Results
- F. Biomonitoring brochure (English and Spanish versions)
- G. Letter from the Scientific Guidance Panel Chair supporting Biomonitoring California priorities.
- H. List of acronyms used in this report

Table of Figures

Figure 1. Biomonitoring California Departmental Roles and Lead Responsibilities 12

Table of Tables

Table 1. Biomonitoring California's Budgets for FY 2009-2011 14

Table 2. Biomonitoring California Staffing for FY 2009-2011 14

Table 3. Current Chemical Testing Methods Used in Biomonitoring California Laboratories 26

Executive Summary

People come into contact with many chemicals each day through using common materials such as personal care products, plastic items and cleaning agents, as well as consuming food and water. Biomonitoring measures chemicals in people's blood, urine, or other biological specimens to help determine which chemicals are present and in what amount. The California Environmental Contaminant Biomonitoring Program, also known as Biomonitoring California is a collaborative effort involving the California Department of Public Health (CDPH), the Office of Environmental Health Hazard Assessment (OEHHA), and the Department of Toxic Substances Control (DTSC). Biomonitoring California is the only ongoing legislatively mandated state biomonitoring program in the country. In SB 1379 (Perata, 2006 Session, chaptered as California Health & Safety Code sections 105440 et seq.), which established Biomonitoring California, the Legislature found that:

"…the establishment of a statewide biomonitoring program will assist in the evaluation of the presence of toxic chemicals in a representative sample of Californians, establish trends in the levels of these chemicals in Californians' bodies over time, and assess effectiveness of public health efforts and regulatory programs to decrease exposures of Californians to specific chemical contaminants. "

Measuring environmental chemicals in California residents will help scientists and policymakers answer such questions as:

- Which chemicals are in people's bodies and how high are the levels?
- Are the levels of chemicals changing over time?
- Are there groups or subpopulations in California that have higher exposures to specific toxic chemicals?
- Do regulatory efforts, including bans or phase-outs of chemicals, actually reduce exposures?
- Do certain chemicals contribute to the development of chronic diseases or conditions?

The principal goals of Biomonitoring California are to monitor, analyze, and report on specific environmental chemicals detected in blood, urine and potentially other biological specimens from a representative statewide sample of Californians and to assess the effectiveness of existing public health programs in reducing these chemical exposures. The Program is required to submit progress reports every two years to the Legislature, beginning in January 2010. This document is the second of these reports.

Program Structure and Resources

CDPH is the lead entity, with primary responsibility for: (1) overall design of the biomonitoring program, including both statewide and community surveys; (2) participant recruitment and sample collection; (3) receipt, storage and analysis of blood and urine samples for metals and chemicals that are not biologically persistent; (4) quality assurance and interpretation of laboratory test results; (5) communication of test results to participants; (6) data analysis; (7) generation of reports to the Legislature; and (8) dissemination of information to the public.

OEHHA has primary responsibility for: (1) administering and supporting the Scientific Guidance Panel; (2) evaluating and summarizing scientific information for the SGP's deliberations on chemicals for biomonitoring; (3) evaluating and summarizing scientific information used in returning test results to study participants (4) collaborating with CDPH on study design and data analysis; and (5) conducting public outreach efforts, including the program website.

DTSC has primary responsibility for: (1) analysis of blood samples for biologically persistent chemicals, and (2) quality assurance and interpretation of the laboratory's test results.

Biomonitoring California was envisioned in SB 1379 to include a statewide survey, in which the Program would measure levels of environmental chemicals in blood, urine, and possibly other biological specimens obtained from a representative sample of California residents. By successfully acquiring supplemental extramural support through a cooperative agreement with the U.S. Centers for Disease Control and Prevention (CDC), Biomonitoring California has been able to undertake smaller-scale community-based studies. The Cooperative Agreement's award period spans 2009-2014, with funding contingent upon available federal resources and adequate programmatic progress.

Scientific Guidance Panel

A nine-member Scientific Guidance Panel (SGP) appointed by the Governor and the Legislature provides technical peer review for the Program. SGP meetings provide opportunities for Biomonitoring California staff to update Panel members and the public on Program activities, request feedback and recommendations from the SGP members, and receive public comments. The SGP has played a critical role in advising the Program in many areas, including study design, collaborations with other researchers, reporting results to participants, and selection of chemicals for biomonitoring.

Study and Sample Design

During 2010-2011 Biomonitoring California staff conducted three pilot studies:

- Program staff collaborated with researchers from the University of California (UC), Berkeley and the UC San Francisco Program on Reproductive Health and the Environment on a pilot project in San Francisco County assessing exposures of 92 pregnant women and their infants to over 70 chemicals.
- Working with UC Irvine Center for Occupational and Environmental Health and the Orange County Fire Authority, staff conducted a project to measure levels of more than 75 chemicals in 100 Orange County firefighters.
- Biomonitoring California is collaborating with the Kaiser Permanente Northern California Research Program for Genes, the Environment and Health on a biomonitoring survey of California's Central Valley. Participants are similar in age, gender, and race/ethnicity to the general population in this region. This is the Program's first effort to obtain a sample representing the population of a large geographic region of the state.

The Program is exploring other methods of approximating a statewide survey. This includes examining whether blood samples collected through the State's Prenatal Screening Program (approximately 400,000 women annually) or dried blood spots from the Newborn Screening Program (approximately 500,000 infants annually) could be used for population-based biomonitoring surveillance.

A distinctive feature of Biomonitoring California is the requirement that biomonitoring results be returned to study participants who request them. The Program is collaborating with researchers at UC Berkeley and others to develop best practices and materials for returning individual test results to participants.

Laboratory Status

CDPH's Environmental Health Laboratory (EHL) and DTSC's Environmental Chemistry Laboratory (ECL) have implemented state-of-the-art testing methods for several types of chemicals in biological specimens. They have also developed standard operating procedures and quality assurance measures for chemicals analyzed as part of biomonitoring studies. Supplemental funding through the CDC Cooperative Agreement has allowed substantial augmentation in both laboratory capacity (i.e., the number of samples that can be analyzed in a given time) and capability (i.e., the types of chemicals that the laboratory can measure).

Public Participation Activities

Biomonitoring California staff has finalized a Public Involvement Plan (PIP) with goals and objectives that will guide the Program's efforts and activities. Staff also developed a brochure to provide basic information about the Program. Links to electronic versions

of the PIP and brochure are available in the report.

A main portal for information about Biomonitoring California is the Program website, which provides public access to materials from past and upcoming SGP meetings and other Program activities. In addition, more than 750 stakeholders regularly receive Program email updates via the Biomonitoring California listserv.

Conclusions

In the years January 2010-December 2011, Biomonitoring California has made significant progress. Specifically, the program has:

(i) greatly increased laboratory capability to analyze environmental chemicals;
(ii) collaborated with several researcher partners;
(iii) made significant progress on two targeted biomonitoring studies as well as a survey representing the population in a large region of California;
(iv) detected elevated levels of mercury in the blood of a mother and infant in one of our studies which resulted in the two being referred to medical care providers; and
(v) expanded outreach and developed materials to communicate biomonitoring results to study participants.

Notwithstanding the significant growth and development supported by CDC funding, the biggest challenge facing Biomonitoring California continues to be identifying sufficient stable, long-term resources to implement the mandate of the enabling legislation for a statewide biomonitoring survey and to continue operation of its complex laboratory infrastructure and functions. Biomonitoring California staff will continue to leverage State resources to acquire external funding to support and expand community and regional biomonitoring studies. Community-based projects focusing on specific populations add value by highlighting exposures in groups at particularly high risk for possible harmful effects from environmental chemical exposure; such studies provide information on chemical exposures in vulnerable populations and can inform environmental justice policies. Regional surveys complement community studies by providing information about exposures in large portions of California's diverse population. Surveys that represent the entire state's population are also needed to evaluate the effectiveness of California's environmental regulatory programs and provide information about environmental chemicals that pose the greatest hazards.

Note – this report covers the period through 2011 – subsequent reports will update this information. For updates about Biomonitoring California, visit our website at: http://oehha.ca.gov/multimedia/biomon/index.html.

I. Introduction and Background

A. Introduction

Biomonitoring is the science of measuring chemicals in blood, urine, or other biological specimens. The California Environmental Contaminant Biomonitoring Program, also known as Biomonitoring California, offers important public health information that cannot be provided by traditional monitoring of air, water, soil or other environmental media. Biomonitoring California was established through legislation in 2006 by Senate Bill (SB) 1379 (Perata) and codified in Health & Safety Code (H&SC) Sections 105440 *et seq.* (see Appendix A).

Under SB 1379, Biomonitoring California is a collaborative effort involving the California Department of Public Health (CDPH), the Office of Environmental Health Hazard Assessment (OEHHA), and the Department of Toxic Substances Control (DTSC), with technical advice and peer review provided by a Scientific Guidance Panel (SGP), and substantial opportunities for input by the public.

Direct measurements of environmental chemicals in people, combined with information on chemical toxicity and likely exposure sources, can help scientists and policymakers answer such questions as:

- What chemicals are people exposed to and are these levels increasing or decreasing over time?
- Do some groups in California have higher exposures to specific toxic chemicals compared to others or to the state's population as a whole?
- Do regulatory efforts, including bans or phase-outs of chemicals, actually reduce exposures among Californians?
- Are certain chemicals contributing to the development of disease?

California residents experience some exposures to environmental chemicals that are different, either qualitatively or quantitatively, from the rest of the country. For instance, California residents have some of the world's highest exposures to long-lived flame retardant chemicals as a result of our state's unique furniture flammability requirements. Biomonitoring can help assess the extent of these and other exposures from all sources, including consumer products, diet, and occupation. It is expected that biomonitoring will play a key role in assessing the efficacy of a number of recent measures to reduce specific chemical exposures, and in helping to inform the state's efforts to identify and regulate chemicals of concern in consumer products.

Biomonitoring California's enabling legislation requires biennial reports to the Legislature. Specifically, H&SC Section 105459(a) states:

> "*By January 1, 2010, and every two years thereafter the department* [CDPH], *in collaboration with the* [California Environmental Protection] *Agency, the Office* [OEHHA] *and DTSC*, *shall submit a report to the Legislature containing the findings of the program, and shall include in the report additional activities and recommendations for improving the program based upon activities and findings to date. Copies of the report shall be made available via appropriate media to the public within 30 calendar days following its submission to the Legislature."*

This report is intended to inform the Legislature and the public of the current status of Biomonitoring California and includes information about its activities and findings during calendar years 2010 and 2011.

B. Background

California residents experience widespread exposures to a multitude of environmental chemicals, such as flame retardants, pesticides, mercury, and substances used in manufacturing plastics, many of which pose health concerns. Recognizing that Californians' health can be improved by reducing exposures to harmful chemicals, the Legislature and the Governor established Biomonitoring California, which is the first legislatively mandated, ongoing state biomonitoring program in the country.

The principal goals of Biomonitoring California are to monitor the levels of specific environmental chemicals in a representative statewide sample of Californians, conduct studies of targeted subpopulations within the state and to help assess the effectiveness of existing public health programs in reducing these chemical exposures. When fully implemented, Biomonitoring California will:

1. Produce information on the levels of environmental chemicals in Californians and whether these levels differ among sub-populations or over time.
2. Offer insights into possible exposure sources that may contribute to the levels of environmental chemicals found in California residents.
3. Assist policymakers in determining the effectiveness of California's environmental regulatory programs and in taking future actions to reduce the exposure of Californians to harmful chemicals.
4. Produce data that researchers will be able to use to help study relationships between levels of chemicals in Californians and health effects.
5. Facilitate the identification of emerging environmental health issues.

Resources available to the Program are insufficient to undertake statewide surveys for the foreseeable future. As described in the following sections, Biomonitoring California is undertaking a number of smaller-scale projects that in themselves will provide valuable information and will also establish a strong foundation for statewide surveys in the future.

II. Program Structure and Resources

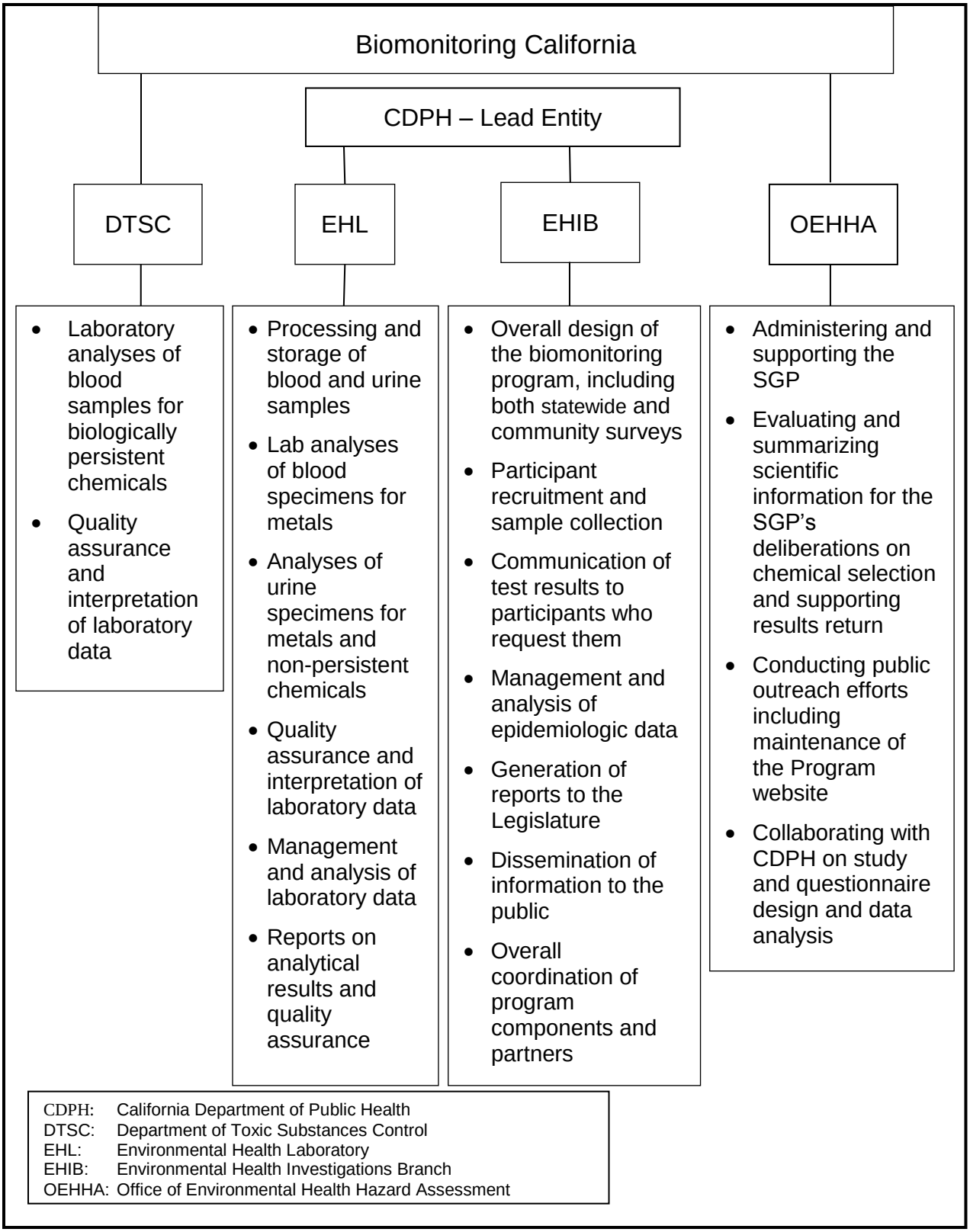
A. Program Structure

SB 1379 requires that Biomonitoring California be developed and implemented collaboratively by CDPH, OEHHA, and DTSC. Staff members from the three departments constitute the Biomonitoring Interagency Group (BIG), which meets twice per month to coordinate activities.

General roles and staff responsibilities for Biomonitoring California are listed in Figure 1. Staff members in all three departments collaborate on multiple activities, including program design, SGP meetings, and data analysis. For instance, OEHHA and DTSC staff members contribute to the program design for which CDPH is the lead. Similarly, OEHHA convenes the SGP and provides scientific support, while representatives from DTSC and CDPH provide scientific and other programmatic input to meeting content, as well as make presentations to and respond to questions from the Panel. The three departments share responsibility for analyzing data collected by Biomonitoring California, focusing on different scientific issues so that analyses are not duplicative. OEHHA hosts the Biomonitoring California web site (http://oehha.ca.gov/multimedia/biomon/index.html).

The design and implementation of the various elements of Biomonitoring California are iteratively reviewed and evaluated by staff, the SGP, and the public. More details about the work to address program mandates are provided in subsequent sections of this report.

Figure 1. Biomonitoring California Departmental Roles and Lead Responsibilities



B. Program Resources

The three departments initially developed a five-year plan to implement the mandates of SB 1379, focusing on the statewide biomonitoring program (per H&SC Section 105441). This plan entailed collecting data and biological specimens every two years from a representative statewide sampling of Californians. The costs were estimated at $9-10 million per year. However, the legislation stated that program implementation would be contingent upon appropriations provided through the annual Budget Act or other measure, but did not include any dedicated funding or identify a funding source (H&SC Section 105453).

The 2007 Budget Act appropriated $5.2 million for Biomonitoring California's initial planning and program implementation, including $3.3 million in one-time equipment purchases and contracted services. In FY 2008-09, due to the state's fiscal crisis, the Legislature transferred Biomonitoring California's funding source from the General Fund to the Toxic Substances Control Account (TSCA). Program baseline funding was set at approximately $1.9 million.

The Biomonitoring California budget is currently augmented by a cooperative agreement with the U.S. Centers for Disease Control and Prevention (CDC). The Cooperative Agreement's award period spans 2009-2014, with funding contingent upon available federal resources and programmatic progress toward objectives. Activities funded by the CDC Cooperative Agreement are described in Section IV.

Biomonitoring California's baseline TSCA funding supports 13 core staff. CDC Cooperative Agreement funding supported eight staff in FY 2009-10 and 13 staff in FY 2010-11. Tables 1 and 2 below present the allocation of funding and staff among the three departments.

Table 1. Biomonitoring California's Budgets for FY 2009-2011

	CDPH	OEHHA	DTSC	**Total**
FY 2009-10				
TSCA[1]	$938,000	$498,000	$371,000	$1,807,000
CDC[2]	$2,652,487	$0	$0	$2,652,487
Total	**$3,590,487**	**$498,000**	**$371,000**	**$4,459,487**
FY 2010-11				
TSCA	$1,066,000	$596,000	$371,000	$2,033,000
CDC	$1,701,718	$0	$950,769	$2,652,487
Total	**$2,767,718**	**$596,000**	**$1,321,769**	**$4,685,487**

[1] TSCA – Toxic Substances Control Account
[2] 5-year Cooperative Agreement with U.S. Centers for Disease Control and Prevention

Table 2. Biomonitoring California Staffing for FY 2009-2011

	CDPH	OEHHA	DTSC	**Total**
FY 2009-10				
TSCA[1]	8	3	2	13
CDC[2]	8	0	0	8
Total	**16**	**3**	**2**	**21**
FY 2010-11				
TSCA	8	3	2	13
CDC	10	0	3	13
Total	**18**	**3**	**5**	**26**

[1] TSCA – Toxic Substances Control Account
[2] 5-year Cooperative Agreement with U.S. Centers for Disease Control and Prevention

While a 2008 budget trailer bill authorized use of TSCA funds for Biomonitoring California, it did not authorize new fees or an increase in existing fees to cover the Program's costs. Given the current gap between TSCA's annual revenues and expenditures, TSCA cannot indefinitely cover both the current Biomonitoring California allocation and other DTSC program activities intended to be supported by this source of funds. CDPH, OEHHA, and DTSC are attempting to identify stable, long-term funding mechanisms that will both sustain current Biomonitoring California functions and allow the Program to grow and fulfill its legislative mandates.

III. Scientific Guidance Panel and Chemical Selection

A. Scientific Guidance Panel Meetings

As mandated in SB 1379 (H&SC Sections 105448 and 105449), scientific peer review of Biomonitoring California is provided by a nine-member SGP appointed by the

Governor and the Legislature. The SGP plays an indispensable role in recommending chemicals to be included in the biomonitoring program; identifying a sub-set of chemicals that are a priority for biomonitoring in California; providing guidance on the design and implementation of the Program; and reviewing the results and conclusions of biomonitoring studies. Appendix B provides short biographies of current Panel members.

SB 1379 requires the SGP to meet at least three times per year. OEHHA is responsible for convening and staffing the Panel and providing scientific materials to support the SGP's deliberations. The SGP has met thirteen times since the inception of Biomonitoring California:

- December 17, 2007
- June 10, October 24, and December 4 - 5, 2008
- March 2 - 3, July 28 - 29, and October 6, 2009
- February 9, May 24, and November 2, 2010
- March 16, July 14, and November 10, 2011

Meetings have taken place either in Oakland or Sacramento. Meeting agendas, presentations, background materials, transcripts, and recordings (when available) are posted on the Biomonitoring California website (http://www.oehha.ca.gov/multimedia/biomon/agendas.html). Summaries of SGP recommendations from several recent meetings are available on the Biomonitoring California website and in Appendix C.

The SGP adds to the list of "designated chemicals" (H&SC Section 105449(c)) and, from this list, makes recommendations for "priority chemicals" for biomonitoring in California (H&SC Section 105449(a) and (b)) (see explanation of this process below). The SGP also provides feedback on the overall implementation of the program, including the development of laboratory capacity and the design of Biomonitoring California pilot projects. In addition to these ongoing discussion items, a range of special topics has been covered at SGP meetings in 2010 and 2011. At the May and November 2010 meetings, the Panel discussed and commented on the Program's draft Public Involvement Plan. The SGP gave the Program valuable input on understanding and interpreting biomonitoring results as part of the regular November 2010 meeting and at a special workshop held on March 17, 2011. At the March 2011 meeting, the Panel reviewed the Program's template for returning participant test results, which was developed and tested as part of the Maternal and Infant Environmental Exposure Project, described in Section IV below. At the same meeting, the Panel also provided input to Program staff that was designed to aid program planning. The SGP's guidance provides a robust scientific underpinning for Biomonitoring California.

The SGP meetings have also provided an important forum for stakeholders and the public to express their views on choosing chemicals to analyze and on other aspects of the structure and implementation of the Program. In 2011, a new open

public comment period was added to the SGP agenda to allow stakeholders to comment on any biomonitoring-related issues.

B. Chemical Selection

Chemicals tested in Biomonitoring California studies come from the Program's list of "designated chemicals". "Designated chemicals" are defined in the legislation as those included in the CDC's national biomonitoring program, plus additional chemicals recommended by the SGP and adopted by the Program (H&SC Sections 105440(b)(6) and 105449(c)). SB 1379 lays out specific criteria for the SGP to follow in adding chemicals to the designated chemical list, including known or potential exposure to the public, known or suspected health effects, and the need to assess the efficacy of public health actions to reduce exposure to a chemical.

The statute also calls for the SGP to identify "priority chemicals" for biomonitoring in California from the designated chemical list. The SGP recommends priority chemicals based on the degree of potential exposure, the likelihood of health effects, the technical limitations of laboratory detection, or any other criteria the panel may agree to.

Since the Program's inception, the SGP has recommended adding five classes of chemicals, one chemical mixture, and six specific chemicals to the list of designated chemicals. A set of priority chemicals, drawn from the list of designated chemicals, has also been recommended by the SGP. Appendix D provides the Biomonitoring California lists of designated and priority chemicals as of February 2011; these lists incorporate all of the Panel's recommendations to that date. The Panel may recommend adding other chemicals to either the designated or priority chemical list in the future.

The list of priority chemicals includes:

- Lead, cadmium, mercury, and arsenic, which are metals used in many industries and found in a variety of products. Lead was also formerly used in house paint and gasoline, leading to widespread environmental contamination. Mercury exposure comes mainly from eating certain types of fish. These four metals can cause many adverse health effects, including cancer and toxicity to the developing infant or child.

- Diesel exhaust, which causes lung cancer and contributes to a range of other health problems, such as asthma and cardiovascular disease.

- Certain pesticides, including organophosphates such as chlorpyrifos, malathion, and naled; pyrethroids, such as cyfluthrin, permethrin, and resmethrin; and DDT, a banned pesticide that is persistent in the environment, Pesticides have been linked to a range of adverse health effects, such as cancer, developmental toxicity, and damage to the immune system.

- Brominated and chlorinated compounds used as flame retardants, which include polybrominated diphenyl ethers (PBDEs) and chlorinated tris. California's stringent furniture flammability regulations have resulted in substantially greater use of chemical flame retardants in products sold in California than in many other states and countries. Many flame retardants accumulate in humans and in the environment. The world's highest levels of certain flame retardants have been measured in the bodies of Californians. Certain flame retardants are associated with impaired neurological development and learning in young children, decreased fertility in women, endocrine disruption and cancer. Some flame retardants, such as chlorinated tris and deca-BDE, are suspected of causing cancer.

- Environmental phenols, including bisphenol A (BPA), triclosan and parabens. BPA is used in certain plastics and to line some food and beverage cans. Triclosan is widely used in antibacterial soaps. Parabens are used as preservatives in a wide variety of products, including cosmetics, personal care products and pharmaceuticals. These chemicals are suspected of harming health by disrupting hormone systems.

- Perchlorate, a component of rocket fuel that has contaminated drinking water and food throughout the U.S. Perchlorate interferes with the proper functioning of the thyroid gland, which could affect neurological development in young children.

- Phthalates, a group of chemicals used primarily in flexible plastic products. A number of phthalates have been identified as developmental and/or reproductive toxicants. The male reproductive system is especially sensitive to phthalate exposure during development.

- Perfluorinated compounds (PFCs), used in a variety of consumer products, such as non-stick cookware, stain-repellent carpets and clothing, and grease-repellent food containers. Two PFCs, perfluorooctanoic acid (PFOA) and perfluoroctanoic sulfonate (PFOS), have been widely detected in Americans. Based on studies of PFOA and PFOS, there is concern that PFCs may harm the fetus and developing child by impairing growth, brain development, learning, and behavior; decrease fertility and affect hormone balance; and contribute to cancer.

- Cyclosiloxanes are used in applications such as dry cleaning and personal care products and are persistent in the environment. There is a concern that certain cyclosiloxanes may contribute to cancer and affect the reproductive system and other organ systems in the body.

- Three polycyclic aromatic hydrocarbons (PAHs), a chemical class of ubiquitous air pollutants that have been shown to cause cancer.

- Polychlorinated biphenyls (PCBs), a class of chemicals formerly used as coolants and insulating fluids. PCBs persist for many years in the environment and accumulate in people. Exposure today mainly results from eating high-fat foods, such as certain types of meat, fish, and dairy products. PCBs are known to cause cancer, harm the developing child, and disrupt hormone balance.

The Program makes the final decisions on which chemicals to include in a biomonitoring project, taking into account the SGP's recommendations for priority chemicals, laboratory capability and capacity, Program resources and other factors.

IV. Biomonitoring California Study and Sample Design

A. Community Studies

The enabling legislation directs the Program to conduct community-based biomonitoring studies "… contingent on funding" (H&SC section 105441). To undertake such studies, Biomonitoring California has pursued external funding and collaborations with other researchers, including analyzing biological samples routinely collected by other public health programs statewide or in large areas of California. These collaborations are described in more detail below.

1. Archived biospecimens from researchers

In September 2008, Biomonitoring California disseminated a request to researchers throughout the United States to identify those in possession of stored blood or urine specimens collected within the preceding five years from California residents. Biomonitoring California staff has pursued two options for obtaining biospecimens:

- The Program finalized agreements with researchers at three academic institutions, Columbia University, the University of California (UC) Davis, and UC Berkeley, to analyze archived samples for a limited number of chemicals. More information about these investigations and the chemicals analyzed is presented in Section V, subsection E.

- Biomonitoring California has initiated discussions with the Kaiser Permanente Research Program on Genes, Environment and Health (RPGEH) regarding the logistics, costs, and benefits of analyzing archived blood and urine specimens collected.

Biomonitoring California staff will continue to assess the feasibility of analyzing archived biospecimens collected by other programs, considering such factors as how

the specimens have been stored, costs to obtain and analyze the specimens, and appropriate sampling strategies to track chemical trends in California's population.

2. Maternal and Infant Environmental Exposure Project(partially supported by the CDC Cooperative Agreement)

Mothers and infants were identified by the SGP as susceptible populations of particular interest for biomonitoring. In collaboration with the UC San Francisco (UCSF) Program on Reproductive Health and the Environment (PRHE) and the UC Berkeley School of Public Health (SPH), Program staff designed the Maternal and Infant Environmental Exposure Project (MIEEP).

The goals of this project are to:

- Measure selected priority chemicals in the urine and blood of pregnant women and umbilical cord blood of their newborns (cord blood measurements represent fetal exposures);
- Test analytical procedures and program coordination for the selected chemicals;
- Identify potential sources of exposure for a subset of these chemicals;
- Develop and test an approach to convey information and guidance regarding biomonitoring results to study participants (see Results Communication below); and
- Evaluate whether an association exists between exposure to these selected chemicals and either pregnancy or birth outcomes.

The pilot is supported by the CDC Cooperative Agreement and the California Wellness Foundation (TCWF). CDC funding supports: (i) development and testing of two exposure questionnaires (one administered by an interviewer to gather demographic, occupational, diet and other information and one completed by the woman at home to identify products used in her residence), (ii) recruiting and enrolling participants, (iii) collecting urine from pregnant women during their last trimester of pregnancy, (iv) obtaining maternal and umbilical cord blood at the time of delivery, (v) shipping specimens to the Biomonitoring California laboratories, and (vi) analyzing the urine and blood samples for priority chemicals. UCSF PRHE and UC Berkeley obtained additional resources from TCWF to support questionnaire administration, additional data analysis, and development of a best practices results communication framework. The framework will help staff communicate the results of chemical analyses to participants, even when the health implications of those results may be uncertain or unknown.

MIEEP protocols, forms, and questionnaires were reviewed and approved by both the UCSF Committee on Human Research and the California Committee for the Protection of Human Subjects (CPHS). Recruitment of participants began in July 2010 and was completed in June 2011; 92 mothers and newborns were enrolled. Collection of data and biological samples was completed by July 2011. Laboratory testing of

samples and data analysis began in 2011 and will be completed in 2012. A key early finding in this study was the detection of elevated blood mercury in one mother-infant pair. The source of mercury exposure was identified as an adulterated face cream from Mexico, and a Health Alert about these types of creams from Mexico was distributed to health care practitioners and clinics. This case is an excellent illustration of the public health benefits of biomonitoring.

3. Firefighter Occupational Exposures Project (partially supported by the CDC Cooperative Agreement)

The SGP also recommended that the Program consider biomonitoring a chemically exposed occupational group. Firefighters are exposed to toxic chemicals in their work environment more frequently and in higher concentrations than the general population. The Firefighter Occupational Exposures (FOX) Project is being conducted in partnership with the UC Irvine Center for Occupational and Environmental Health and the Orange County Fire Authority. This project is expected to provide information on exposures to environmental chemicals among California firefighters. In addition, the protocols and procedures developed in this pilot study of 101 firefighters will serve as a basis for later and larger occupational biomonitoring efforts.

CDC funds support the design of the FOX Project; field testing project protocols and documents, including an exposure questionnaire; collecting, processing, and shipping blood and urine samples; measuring of chemicals in blood and urine at Biomonitoring California laboratories; and testing and refining methods for returning biomonitoring results to participants in an understandable and meaningful way.

The FOX protocols, forms and questionnaires were reviewed and approved by both the UC Irvine Institutional Review Board and the CPHS. The FOX Project began recruiting participants in fall 2010 and completed data and biosample collection in early 2011. During 2011 and 2012, Biomonitoring California laboratories will be analyzing firefighters' blood and urine samples for heavy metals, brominated flame retardants, perfluorinated chemicals, and selected substances formed during incomplete burning of wood and other materials. Participants completed a short questionnaire to help identify potential sources of exposure for some of the chemicals being biomonitored. In addition, at each fire station with a FOX participant, a firefighter conducted a brief standardized walkthrough evaluation and recorded possible exposure sources to some of the chemicals being measured for this project. To complement the latter effort, a separate funding source allowed staff to collect dust samples from several fire stations. The dust will be analyzed for some of the same chemicals being biomonitored in the firefighters.

B. Results Communication

A distinctive feature of the Program is the statutory requirement to return biomonitoring results to study participants who request them(H&SC Section 105443), even if the health implications of these results are scientifically uncertain. During 2010-

11, Biomonitoring California continued to collaborate with the UC Berkeley SPH to develop and refine approaches for communicating biomonitoring results to study participants.

A draft “report-back template” for communicating results to project participants was developed. The template includes explanatory materials providing participants with visual representations as well as narrative descriptions of their results. Participants are also presented with background information about the chemicals tested, such as potential sources of exposure. The template can be customized for individual projects and communities, as needed. The draft template was developed to convey, simply and clearly, complex biomonitoring findings to participants. Usability testing was conducted to determine the extent to which project participants could find their results and understand the information in the template. This testing was completed during one-on-one meetings with individual participants. The template was refined through a series of usability tests with both English- and Spanish-speaking participants in MIEEP.

Staff and collaborators from the UC Berkeley SPH presented the development and refinement of the template at the March 2011 SGP meeting, and discussed with the Panel some of the challenges that remain. Overall, Panel members expressed their support for the approach and provided positive feedback on the template. To further improve our report-back materials, Program staff conducted further testing of the template materials with participants in the FOX Project. This included evaluating how participants understood graphic representations of the results and various other elements of the report-back materials.

Biomonitoring California is also developing protocols to guide follow-up actions with participants who are identified as having high levels of biomonitored chemicals for which clinical health information is available (lead, cadmium and mercury). The protocol includes notifying participants with high levels of these substances by letter and providing relevant advice regarding additional follow-up, if warranted. Appropriate informational materials, such as a fact sheet on choosing low-mercury fish, are being developed and will be included in communications to participants where needed.

A challenge for Program staff is how to interpret biomonitoring results and convey their potential health implications to participants, particularly for chemicals whose toxicity in humans has not been well studied. In March 2011, Biomonitoring California held a public workshop on understanding and interpreting biomonitoring results, bringing together national experts, the Program’s SGP and the public in a discussion of these issues.

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[1] 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 agenda and a summary of key findings of the workshop are included as Appendix E. Additional information about the workshop, including the presentations, can be found at:
http://www.oehha.ca.gov/multimedia/biomon/sgpwrkshp031711.html

C. Method to Approximate a Statewide Survey

Biomonitoring California's legislatively mandated goals include determining the levels of environmental chemicals in a representative statewide sample of Californians and monitoring those levels over time. However, implementing a statewide biomonitoring program has been limited by California's budget crisis. In order to approximate statewide and regionally representative samples, Program staff is leveraging existing resources by exploring the feasibility of analyzing chemicals in blood specimens previously collected by another state program, and collaborating with Kaiser Permanente Northern California, a large Health Maintenance Organization with a statewide presence.

1. Biomonitoring Exposures Study (BEST) (partially supported by the CDC Cooperative Agreement)

Biomonitoring California is collaborating with Kaiser Permanente Northern California's (KPNC) Research Program on Genes, Environment, & Health (RPGEH) to conduct the pilot project known as BEST. KPNC membership in California's Central Valley is similar to the entire population of northern California in characteristics such as educational attainment and race/ethnicity. BEST will recruit KPNC members who reside in areas of Sacramento, Stockton, Yolo, Modesto, Merced, Madera and Fresno counties. This collaboration is the first time that Biomonitoring California will be recruiting and enrolling participants through a random sampling design that will approximate a representative sample of California's Central Valley.

[1]A "comparison level" is a level of a chemical in blood or urine that can be used to provide context for biomonitoring results or evaluate possible concerns. For example, levels in blood or urine measured in the US national biomonitoring program are useful for providing context. As a second example, CDC has set levels of concern for lead in blood of adults and children, which California uses to evaluate blood lead levels for possible medical follow up.

The goals of this pilot project are to:

- Recruit adult KPNC members in California's Central Valley;
- Obtain questionnaire data as well as biological samples;
- Analyze the blood and urine samples for concentrations of selected priority chemicals; and
- Continue to refine approach to communicating chemical test results to participants, as well as the implications of those results.

BEST will enroll approximately 100 English-speaking adults categorized by age (18-55 and greater than 55 years of age), gender, race/ethnicity (Non-Hispanic whites, African-American, Asian/Pacific Islander, and Hispanic), and residence location (urban/suburban or rural). KPNC members in these categories will be randomly selected and then invited to participate in BEST. Blood and urine samples will be collected from participants, who will fill out a questionnaire to help evaluate possible exposure sources for some of the chemicals being biomonitored. The protocols, forms and questionnaires for this project have been approved by the KPNC Institutional Review Board and the CPHS.

V. Biomonitoring California Laboratory Status

A. Laboratory Organization

CDPH's Environmental Health Laboratory (EHL) in Richmond and DTSC's Environmental Chemistry Laboratory (ECL) in Berkeley conduct the analyses of designated and priority chemicals measured by Biomonitoring California.

EHL has primary responsibility for the development of methodologies for analyzing metals in blood and non-persistent chemicals in blood and urine (Table 2). In addition, EHL has responsibility for developing analytical methods for measuring priority chemicals in DBS and ultra-low volume blood specimens.

ECL serves as California's reference laboratory for analysis of toxic chemicals in the environment, biota and consumer products. Within Biomonitoring California, ECL has primary responsibility for developing analytical methods for persistent chemicals in serum (the liquid part of a blood sample that remains after the blood clots).

B. Instrumentation

Biomonitoring California relies on our laboratories' ability to precisely measure very low concentrations of chemicals in blood and urine. In order to identify emerging chemical exposures, the laboratories must be able to develop new testing methods, as well as insure that they can support the biomonitoring studies described previously.

Biomonitoring data that may influence future chemical policy must be based on advanced analytical procedures conducted with state-of-the-art instruments.

With CDC Cooperative Agreement funding, EHL was able to purchase and install:

- A Gas Chromatography-Mass Spectrometer (GC/MS-MS) to develop a new method for testing organophosphate pesticide breakdown products;
- Two High Performance Liquid Chromatography-Mass Spectrometer (HPLC/MS-MS) instruments – one for developing a test for environmental phenols and one for developing a procedure to test for hydroxy-PAHs;
- An Inductively Coupled Plasma Mass Spectrometer (ICP-MS) to develop methods for testing metals in urine; and
- An Ion Chromatography-Mass Spectrometer (IC-MS/MS) for perchlorate analysis.

CDC Cooperative Agreement funds allowed ECL to acquire:

- A Liquid Chromatography-Mass Spectrometer (LC/MS-MS) to analyze polar persistent contaminants, such as several new flame retardants, environmental phenols and hydroxy-metabolites (breakdown products) of PCBs and PBDEs; and
- Additional auxiliary equipment to be used for sample preparation and extraction.

C. Quality Assurance

The Biomonitoring California Laboratory Quality System incorporates all aspects of quality assurance and quality control for EHL and ECL. Staff funded by the CDC Cooperative Agreement is responsible for tracking laboratory and analyst certifications, overseeing blind audit samples, establishing control limits for audit samples, meeting compliance requirements for recertification, developing protocols and procedures for specimen management to meet the specific needs of the field studies being conducted with Biomonitoring California collaborators, and coordinating participation in laboratory proficiency testing programs.

D. Laboratory Information Management System (LIMS)

Biomonitoring California laboratories will fully operate within a computerized Laboratory Information Management System (LIMS). This system also links sample collection information with analytical results. Recent improvements to the LIMS include adding modules to track samples (e.g., storage locations and test analysis status), developing laboratory reports, and delivering chemical test results securely to other Program staff for data analysis.

E. Current Chemical Testing Methods

The environmental chemical analyses that Program laboratories have developed or revised and validated and that are currently in use are listed in Table 3.

Table 3. Current Chemical Testing Methods Used in Biomonitoring California Laboratories

Chemicals	Specimen	Laboratory*	Date Developed
Lead, Cadmium, Manganese and Total Mercury	Whole Blood	EHL	December 2009
Lead, Cadmium, Manganese and Total Mercury	Urine	EHL	In development
Creatinine	Urine	EHL	March 2010
Chlorpyrifos and Pyrethroid metabolites [Chlorpyrifos metabolite is 3,5,6-trichloro-2-pyridinol (TCPy)] [Pyrethroid metabolite is 3-phenoxy benzoic acid (3-PBA)]	Urine	EHL	February 2010
Phthalate metabolites [monoethyl phthalate (MeP), monobutyl phthalate (MbP),monopentyl phthalate(MPP)]	Urine	EHL	May 2010
Polycyclic Aromatic Hydrocarbon (PAH) metabolite [3-hydroxy-phenanthrene (3-Phen)]	Urine	EHL	June 2010
12 Perfluorinated Compounds (PFCs)	Serum	ECL	June 2010
Major Polychlorinated Biphenyls (PCBs)^	Serum	ECL	March 2011
Major Organochlorine Pesticides (OCPs)^	Serum	ECL	March 2011
Polybrominated Diphenyl Ethers (PBDEs)^	Serum	ECL	March 2011

* EHL = Environmental Health Laboratory (CDPH)
ECL = Environmental Chemistry Laboratory (DTSC)
^ = new laboratory method using High Resolution-Gas Chromatography Tandem Mass Spectrometry (HRGC-MS/MS)

F. CDC Site Visit

The Project Officer for the CDC Cooperative Agreement visited the Biomonitoring California Program in Richmond and Berkeley in March 2011. This site visit allowed staff to provide more detailed information on Program accomplishments, including collaborations with scientists and community groups, progress made toward laboratory methods development, and expansion of laboratory capacity and capability. Staff is now

implementing changes to improve the program based on specific suggestions the Project Officer made following her visit.

G. Analyses of Archived Biospecimens

In 2010 and 2011, EHL analyzed the following chemicals in archived biospecimens:

- 3,5,6-trichloro-2-pyridinol (TCPy), a breakdown product of chlorpyrifos, an organophosphate pesticide widely used in California was collected for a California Environmental Health Tracking Program (CEHTP) project in Tulare County. CEHTP is a program within the CDPH funded by the CDC as part of a national network of state environmental health tracking programs. These programs work to integrate environmental and health data, producing information that is accessible to the public to drive improvements in the health of communities.
- TCPy and breakdown products of phthalates collected by the UC Davis Childhood Autism Risks from Genetics and the Environment (CHARGE) study. CHARGE is a study of 1,100 children and their families in 22 California counties. UC researchers will examine whether selected environmental factors are associated with child development, specifically with regard to autism and developmental delay.
- Breakdown products of phthalates collected by the UC Berkeley Center for the Health Assessment of Mothers and Children of Salinas (CHAMACOS). CHAMACOS is a study examining environmental exposures and the health of low-income children in the Salinas Valley. EHL also conducted quality control studies to ensure that samples were not contaminated during collection or processing.
- Metals (lead, cadmium and mercury) in blood were analyzed for 500 participants in CYGNET (Cohort study of Young Girls' Nutrition, Environment, and Transitions), a collaboration with KNPC staff and other researchers looking at early environmental exposures and pubertal maturation in girls.

VI. Public Participation Activities

H&SC Section 105451 directs Biomonitoring California to “provide opportunities for public participation and community capacity building” to allow for “meaningful stakeholder input” and to “develop a strategy and plan … to establish the framework for integrating public participation in this program.”

In accordance with the directive of H&SC Section 105451 “to establish the framework for integrating public participation”, a draft of the Public Involvement Plan was posted on the Program website in September 2010 for public review. The Plan was presented to the SGP in November 2010. Biomonitoring California solicited public comment on the draft Plan via multiple avenues, including two teleconferences and an on-line survey. The Plan includes goals and objectives to guide Biomonitoring

California's efforts, as well as specific activities to be carried out as resources allow. More than 200 comments on the Plan were received by the January 25, 2011 deadline. The comments were reviewed in detail and used to refine and improve the Plan. The finalized Plan, available online at http://www.oehha.ca.gov/multimedia/biomon/biomonpublic.html, provides an overview of the broad range of public involvement efforts being carried out by Biomonitoring California.

As outlined in the Public Involvement Plan, Program staff has begun planning ways to expand stakeholder involvement in Biomonitoring California and to explore building collaborative partnerships to enhance Program activities. Staff developed a brochure titled "What is Biomonitoring? Measuring Chemicals in Our Bodies" that describes basic information about the Program. The brochure is available in both English and Spanish as part of this document (see Appendix F) and on the Program website (English version: http://www.oehha.ca.gov/multimedia/biomon/pdf/2011BiomonBrochure_English.pdf , Spanish version: http://www.oehha.ca.gov/multimedia/biomon/pdf/2011BiomonBrochure_Spanish.pdf).

As an initial step, Biomonitoring California conducted an online needs-assessment survey to determine stakeholder preference for different ways of participating in Program meetings. Survey results indicated a regional clustering of current stakeholders in Northern California and a preference for meetings via teleconference and webinars rather than in-person venues.

Biomonitoring California maintains and updates a Program-specific website (http://www.biomonitoring.ca.gov) and listserv (electronic mailing list). The website provides general information about the Program and gives the public access to materials from past and upcoming public workshops, SGP meetings, and other opportunities to participate. Individuals interested in staying informed about the Program are invited to join the listserv via a link on the website. The listserv included approximately 760 active subscribers as of August 2011. The Program sends notes to listserv subscribers about upcoming events, new materials posted on the website, and other activities of potential interest. The public can communicate with the Program through our email address, biomonitoring@oehha.ca.gov.

Efforts are underway to make the website more user-friendly and accessible. In 2010, UC Berkeley SPH Health Research for Action (HRA) conducted a structured analysis of the Biomonitoring California website to improve its usability. HRA also carried out a discovery process with internal stakeholders regarding the needs of the Program and specific requirements affecting design of this site. Program staff has worked with HRA to develop a detailed design plan for revising the website. The website revision will improve navigation, ease of use, accessibility, and relevance of the site for a general audience.

To allow for remote access to SGP meetings and Biomonitoring California workshops during 2010-11, Program staff used a range of technologies, including video- and audio-webcasting, videotaping, and use of a webinar format. Individuals participating remotely can comment on the agenda items via email. The Program provided webinar access to the SGP meeting and workshop held in March 2011. A workshop on manganese held in June 2011 also used a webinar format. The March 2011 workshop on understanding and interpreting biomonitoring results was videotaped, to capture the presentations and discussions for viewing by those unable to attend the workshop and others who may have an interest in the material in the future.

VII. Conclusions and Recommendations

During the last two years (January 2010-December 2011), Biomonitoring California has made considerable progress. Specifically, the program has:

(i) significantly increased laboratory capability to analyze priority environmental chemicals;
(ii) collaborated with University of California partners on analyses of archived biospecimens;
(iii) initiated community-based as well as regional biomonitoring surveys;
(iv) detected elevated levels of mercury in the blood of a mother and infant in one of our studies;
(v) convened six SGP meetings;
(vi) added manganese, pendimethalin and triclocarban to the designated list and four parabens and certain PCBs to the priority list, based on the SGP's recommendations; and
(vii) provided enhanced opportunities for public involvement.

The Program has also substantially advanced its efforts to expand outreach and develop materials to communicate biomonitoring results clearly, especially to study participants. Individual biomonitoring results will be returned to study participants and summarized group data will be disseminated publicly beginning in 2012.

Many of the recent accomplishments were supported by resources available through the five-year CDC Cooperative Agreement.

Listed below are Program priorities for maintaining and improving Biomonitoring California. The SGP supports these recommendations (Appendix G).

A. Program Resources – Continue to:
- pursue external funding opportunities to supplement State support.
- pursue collaborations with other researchers that leverage existing resources.

B. Laboratory Analyses – Continue to:
- Conduct activities specified in the CDC Cooperative Agreement to allow Biomonitoring California to measure additional groups of chemicals and analyze samples from a greater number of individuals.
- collect biological samples and analyze biomonitoring data.
- pursue collaborations to develop laboratory methods to screen for a broad range of chemicals in Californians. This could provide a potentially important tool in the selection of chemicals for biomonitoring studies.

C. Public Participation – Continue to:
- identify and engage additional stakeholders and encourage their involvement in program development and implementation.
- maintain and expand Biomonitoring California's electronic resources, including: website improvements and internet broadcasting or audio-casting of SGP meetings whenever possible,
- increase numbers of listserv subscribers, and conduct more surveys of subscribers to identify Program-related needs and concerns.

D. Scientific Guidance Panel – Continue to:
- convene SGP meetings three times per year to provide Panel members with information and the opportunity to make recommendations to Biomonitoring California, as well as provide the public with additional occasions to comment on program activities.
- research and develop materials to support the SGP in selecting designated and priority chemicals to include in Biomonitoring California.

E. Results Communication – Continue to:
- refine results communication methods and materials for individual participants, health-care providers, and the general population.
- develop scientifically accurate information on potential health concerns of biomonitored chemicals and likely exposure sources, as well as guidance on how to reduce exposures to harmful chemicals.

Biomonitoring California staff will continue to leverage State resources by securing cooperative agreements and other external funding to support and expand community-based and regionally representative biomonitoring studies.

Studies that focus on particular populations add value by highlighting exposures in groups at particularly high risk to possible harmful effects from exposure to environmental chemicals. Surveys that represent large areas of the state provide important information about exposures in California's diverse population. Finally, surveys that represent the entire state's population are also needed to provide the basis for evaluating the effectiveness of California's environmental regulatory programs and to help provide information about environmental chemicals that pose the greatest hazards.

APPENDICES

A. Health and Safety Code (Division 8, Part 5, Chapter 8, Section 105440, et seq. (SB1379))

B. List of SGP members and short biographies

C. Summaries of recommendations made by panel members at recent SGP meetings

D. Biomonitoring California's lists of designated and priority chemicals for biomonitoring

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

F. Biomonitoring brochure (English and Spanish versions)

G. Letter from the Scientific Guidance Panel Chair supporting Biomonitoring California priorities.

H. List of acronyms used in this report