

IMPLEMENTATION OF THE CALIFORNIA ENVIRONMENTAL
CONTAMINANT BIOMONITORING PROGRAM

**Narrative of
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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I. Introduction and Background

A. Introduction

Biomonitoring is the science of measuring chemicals in humans. By directly measuring levels of potentially toxic environmental chemicals in blood, urine, or other biological specimens, biomonitoring can produce important public health information that cannot be provided by traditional air, water, and soil monitoring. The California Environmental Contaminant Biomonitoring Program (CECBP) was established through legislation in 2006 by Senate Bill (SB) 1379 (Perata, Chapter 599, Statutes of 2006; codified in Health & Safety Code (H&SC) Sections 105440 through 105459 – see Appendix A). Under SB 1379, the CECBP 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 distinguished Scientific Guidance Panel (SGP), and substantial opportunities for input by the public.

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

- What chemicals are people exposed to?
- Which groups or populations in California have higher exposures to specific toxic chemicals?
- 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 now have 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 consumer products, diet, occupation, and other sources. 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 shape the state's nascent Green Chemistry Initiative.

The CECBP'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 the CECBP and includes information about its activities and findings through calendar year 2009.

B. Background

California residents experience widespread exposures to a multitude of environmental chemicals, such as flame retardants, pesticides, mercury, and plasticizers, 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 the tri-departmental CECBP. The CECBP is the first legislatively mandated, ongoing state biomonitoring program in the country.

The principal goals of the CECBP 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. When fully implemented, the CECBP will:

1. Produce information on the levels of environmental chemicals in Californians and whether those levels are increasing or decreasing over time.
2. 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 in the environment.
3. Produce data that researchers could use in studying relationships between levels of chemicals in Californians and health effects.
4. Facilitate the identification of emerging environmental health issues.

Resources available to the program are insufficient to undertake statewide surveys for the foreseeable future. Nonetheless, as described in the following sections, the CECBP is undertaking a number of smaller-scale projects that will provide valuable information in themselves and will also lay a strong foundation for statewide surveys in the future.

II. Program Structure and Resources

A. Program Structure

SB 1379 requires that the CECBP be collaboratively developed and implemented 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 are listed in Figure 1.

Figure 1. CECBP Departmental Roles and Lead Responsibilities

CDPH (lead entity) – (1) overall design of the biomonitoring program, including both statewide and community surveys; (2) participant recruitment and sample collection; (3) communication of test results to participants who request them; (4) data management and analysis; (5) generation of reports to the Legislature; and (6) dissemination of information to the public.

DTSC, CDPH laboratories – Laboratory methods development, processing and analyzing biological samples for environmental contaminants, and data analysis

OEHHA – (1) administering and supporting the Scientific Guidance Panel, including scientific evaluation of information used to select chemicals for biomonitoring; (2) developing public outreach efforts, including maintenance of the program website and dissemination of information to the public; (3) carrying out data analysis; and (4) identifying levels of biomonitored chemicals in blood or urine that may be of health concern.

Staff members in all three departments collaborate on multiple activities within the overall division of labor, including program design, SGP meetings, and data analysis. For instance, OEHHA and DTSC staff contribute to the program design for which CDPH is the lead. Similarly, though OEHHA convenes and staffs the SGP meetings, representatives from DTSC and CDPH attend and make presentations to the Panel as well. Departmental responsibilities for analysis of data to be collected by the CECBP will be non-duplicative and will focus on different issues.

CECBP activities and issues 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.

B. CECBP Budget

At the present time, CECBP does not have sufficient resources to implement the statewide biomonitoring program mandated in SB 1379 (H&SC Section 105441). The legislation stated that program implementation would be contingent upon appropriations provided through the annual Budget Act or other measures, but did not include any dedicated funding (H&SC Section 105453). The three departments initially developed a five-year implementation plan aimed at beginning operations of the full program (collecting data and biological specimens from approximately 2000 participants per two-year sampling cycle) in Fiscal Year (FY) 2011-12.

The 2007 Budget Act provided an appropriation of \$5.2 million for CECBP planning and initial program implementation, \$3.2 million allocated to CDPH, \$380,000 allocated to OEHHA and \$1,600,000 allocated to DTSC. Much of this allocation consisted of one-

time funding for the acquisition of dedicated equipment for the CDPH and DTSC laboratories. Due to the state's fiscal crisis, the Legislature transferred the source of CECBP's funding from the General Fund to the Toxic Substances Control Account (TSCA) in FY 2008-09. TSCA was established to finance state Superfund cleanup and pollution prevention activities, but trailer-bill legislation (AB 1338, Chapter 760, Statutes of 2008) specifically amended H&SC Section 25173.6(b)(16) to allow funding of the CECBP from TSCA. The TSCA fund receives revenue primarily from environmental fees levied on businesses with 50 or more employees that handle hazardous materials and cost recovery of DTSC's work on hazardous substance release sites. Currently, TSCA annual revenues do not cover annual expenditures.

CECBP's baseline TSCA funding of approximately \$1.9 million per year supports 13 core staff. Table 1 presents the allocation of funding and staff among the three departments.

Table 1. CECBP Budgets for FY 2007-2009

	CDPH		OEHHA		DTSC		Total	
	Budget	Staff	Budget	Staff	Budget	Staff	Budget	Staff
FY 2007-08 ¹ Initial budget with 2007 legislative augmentation								
Baseline	\$954,000	8	\$380,000	3	\$368,000	2	\$1,702,000	13
One-time only costs	\$2,246,000		\$0		\$1,232,000		\$3,478,000	
Total	\$3,200,000	8	\$380,000	3	\$1,600,000	2	\$5,180,000	13
FY 2008-09 ²								
Baseline & Total	\$1,029,000	8	\$558,000	3	\$344,000	2	\$1,931,000	13
FY 2009-10								
Baseline ²	\$1,062,000	8	\$558,000	3	\$344,000	2	\$1,964,000	13
CDC ³	\$2,600,000	9	0	0	0	0	\$2,600,000	9
Total	\$3,662,000	17	\$558,000	3	\$344,000	2	\$4,564,000	22

¹ General Fund

² Toxic Substances Control Account

³ 5-year Cooperative Agreement with U.S. Centers for Disease Control and Prevention

While the 2008 trailer-bill legislation authorized use of TSCA funds for CECBP, it did not authorize new fees or an increase in existing fees to cover the program's costs. It also did not specify any amount of funding that should be allocated to CECBP. Given the current gap between TSCA annual revenues and expenditures, TSCA cannot indefinitely cover both the current CECBP allocation and other DTSC program activities intended to be funded from TSCA. Moreover, current state support for the CECBP is only a fraction of the amount needed to operate the full program mandated by SB 1379, including statewide surveys (estimated between \$9M and \$10M/year). It appears that TSCA, as currently constituted, is at best only a temporary funding source for CECBP and does not represent a stable, long-term funding source for the program.

CDPH, OEHHA, and DTSC are attempting to identify a stable, long-term funding mechanism that will both sustain current CECBP functions and allow the program to grow and fulfill its legislative mandates. Such a funding mechanism, once identified, will likely require legislation.

In light of the state's current fiscal difficulties, CECBP staff have sought and obtained extramural financing to conduct smaller-scale biomonitoring activities. In a competitive application process, CECBP worked with the non-profit organization Sequoia Foundation, which resulted in the award of a five-year cooperative agreement with the U.S. Centers for Disease Control and Prevention (CDC), beginning September 1, 2009. The other states awarded cooperative agreements are New York and Washington. The purpose of the cooperative agreement is to increase state biomonitoring laboratory capability and capacity. The CDC has indicated that this funding is intended to supplement, not replace, existing state biomonitoring program support. This funding (\$2.6 million for federal FY 2009-10) will be used primarily to hire Sequoia Foundation staff at the CDPH Richmond campus, purchase laboratory equipment and supplies, and provide resources for collecting biological specimens (blood and urine) from California residents. Funding for the remaining four years of this agreement will depend upon the availability of federal resources, which is reevaluated annually. During the second through fifth years of the cooperative agreement, available funds will support the DTSC laboratory in addition to the activities identified during FY 2009-10.

Activities to be funded by the CDC cooperative agreement are described in Section IV. While the agreement will provide for needed laboratory equipment and initial biomonitoring data covering certain groups of Californians, the CDC funds will not be sufficient to operate a statewide biomonitoring program on an ongoing basis.

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 the CECBP is provided by a nine-member Scientific Guidance Panel (SGP) appointed by the Governor and the Legislature. The purpose of the SGP is to recommend chemicals to be included in the biomonitoring program, provide input and guidance on the design of the program, and to review the results and conclusions of biomonitoring studies. The SGP has played an indispensable role in identifying and recommending priority chemicals for biomonitoring by the CECBP. Appendix B contains a list of names and short biographies for current Panel members.

SB 1379 requires the SGP to meet three times per year. OEHHA is responsible for convening, staffing, and providing background materials for the SGP meetings. Since the inception of the CECBP, the SGP has met seven times:

- December 17, 2007;
- June 10, October 24, and December 4 - 5, 2008;
- March 2 - 3, July 28 - 29, and October 6, 2009.

Meetings have taken place either in Oakland or Sacramento. Meeting agendas, presentations, background materials, transcripts, and recordings (when available) are posted on the CECBP website, which is hosted and maintained by OEHHA (<http://oehha.ca.gov/multimedia/biomon/index.html>). Summaries of SGP recommendations from several recent meetings are available on the CECBP website and in Appendix C.

The primary SGP actions to date have been to augment the list of “designated chemicals” (H&SC Section 105449(c)) and, from this list, to make recommendations for priority chemicals for biomonitoring in California (H&SC Section 105449(a) and (b)) (see below). The SGP has also heard progress reports and provided feedback on the overall implementation of the program, including the development of laboratory capacity and the CECBP program choices to analyze archived biological specimens and to undertake a pilot mother-infant biomonitoring study. The SGP meetings have also provided a forum for stakeholders and the public to express their views on chemical selection and the structure of the program.

B. Chemical Selection

Selection of chemicals for biomonitoring by the CECBP involves a two-step process, defined in the enabling legislation (H&SC Section 105449). In the first stage of the selection process, chemicals of interest are considered for inclusion in a list of “designated chemicals.” Only a “designated” chemical can be biomonitored. Designated chemicals are defined in the legislation as those included in the CDC’s national biomonitoring program, plus additional chemicals as recommended by the SGP and adopted by the program (H&SC Sections 105440(b)(6) and 109449(c)). These additional chemicals can be designated based on known or potential exposure to the public, known or suspected health effects, and other criteria contained in SB 1379.

SB 1379 sets out a second stage in the process, by providing for the selection of “priority chemicals” for biomonitoring from the list of designated chemicals. The SGP may recommend priority chemicals based on the degree of potential exposure, the likelihood of health effects, the limits of laboratory detection, and other criteria the panel may agree to. CECBP staff retains authority for final choices on chemicals to be biomonitored from the pool of priority chemicals.

To date, the SGP has added five classes of chemicals, one chemical mixture, and three 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 a complete list of CECBP designated and priority chemicals as of

December 2009. The Panel may add other chemicals to either the designated or priority list in the future.

The list of priority chemicals includes substances in a range of chemical classes, with highlights shown below:

- Lead, cadmium, mercury, and arsenic, which are present in a variety of products and used in a number of industries. Exposure to these metals or compounds of these metals can cause many adverse health effects, including cancer and reproductive effects.
- Diesel exhaust, which has been linked to a number of ailments, including cancer.
- Cotinine, which is an indicator of recent exposure to tobacco smoke.
- Certain pesticides, including organophosphate pesticides such as chlorpyrifos, malathion, and naled, and pyrethroid pesticides, such as cyfluthrin, permethrin, and resmethrin.
- Brominated and chlorinated compounds used as flame retardants, which include polybrominated diphenyl ethers (PBDEs) and the carcinogen chlorinated tris, for example. Many flame retardants accumulate in the body and in the environment and some are suspected of causing cancer and impacting child development. California fire-safety regulations result in substantially greater use of chemical flame retardants in products sold in California than in many other states and countries.
- Environmental phenols, including bisphenol A (BPA) and triclosan. BPA is used in certain plastics and to line some food and beverage cans. Triclosan is widely used in antibacterial soaps. These chemicals are suspected of disrupting hormone systems and consequently harming health.
- Perchlorate, a component of rocket fuel that may contaminate drinking water and food. Perchlorate interferes with the proper functioning of the thyroid gland, which could affect child development.
- Phthalates, a family of chemicals used in cosmetics and plastic products. A number of phthalates have been identified as developmental and/or reproductive toxicants. The development of the male reproductive system appears to be especially sensitive to phthalate exposure *in utero*.
- Perfluorinated compounds (PFCs), used to manufacture non-stick cookware, wrinkle-free clothing, and other consumer products. One such compound, perfluorooctanoic acid, has been detected in virtually all Americans, and may cause cancer and reproductive effects.

- Cyclosiloxanes, which are used in applications such as dry cleaning and personal care products. For certain cyclosiloxanes, there are concerns for potential carcinogenicity, possible effects on the reproductive system, and effects on other systems in the body. Cyclosiloxanes are also persistent in the environment.
- Three polycyclic aromatic hydrocarbons, a family of chemicals that are ubiquitous air pollutants and have been shown to cause cancer.

For some of the above classes, not all members of the chemical class are priority chemicals. For specific details on chemicals included on the priority list, please refer to Appendix D.

IV. CECBP Study and Sample Design

A. Community studies

In addition to obtaining biomonitoring data representative of the general California population, H&SC Section 105441 states that community-based studies “shall be contingent on funding.” To undertake such studies, CECBP 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 further described below. Projects supported by the CDC Cooperative Agreement are marked with an asterisk (*).

1. Archived biospecimens from researchers

In September 2008, CECBP disseminated a request to researchers throughout the United States to identify those with stored blood or urine specimens collected within the past five years from Californian residents. The CECBP laboratories will use their recently purchased equipment and apply their model analytical protocols to produce biomonitoring data on Californians’ chemical exposures in 2010. CECBP staff is pursuing two options for obtaining biospecimens:

- a. CECBP is finalizing agreements with researchers at three academic institutions -- Columbia University, UC Davis, and UC Berkeley -- to analyze archived samples for a limited number of chemicals. More information about these investigations and the chemicals to be analyzed is presented in Section V.E.
- b. CECBP has initiated discussions with CDPH’s Genetic Disease Screening Program and the Kaiser Permanente Research Program on Genes, Environment and Health (RPGEH). Blood and urine specimens from Kaiser Permanente members in northern California may be available for chemical analysis.

CECBP staff will continue to assess the feasibility of obtaining biospecimens to analyze, considering such factors as the utility of the specific specimens for the analysis of

selected chemicals, costs to obtain and analyze the biospecimens, and appropriate sampling strategies to allow for tracking chemical trends in California's population.

2. Maternal and Infant Environmental Exposure Project*

In response to recommendations from CECBP's SGP and members of the public, CECBP has designed a pilot project to measure selected priority chemicals in pregnant women and in umbilical cord blood during delivery. Chemicals measured in umbilical cord blood represent those in the newborn infant; cord blood can be obtained in substantial quantities just after delivery without harming the neonate. This would provide valuable information on the degree to which fetuses are exposed to environmental chemicals that could affect their development. Using funding available through the CDC cooperative agreement, CECBP plans to conduct the Maternal and Infant Environmental Exposure Project (MIEEP) collaboratively with the University of California, San Francisco (UCSF) Program on Reproductive Health and the Environment (PRHE). During the first year of the cooperative agreement, CDC funding will support participant recruitment and enrollment, collection of urine from approximately 100 pregnant women during their last trimester of pregnancy, collection of maternal and umbilical cord blood at the time of delivery, and analysis of selected priority chemicals by CECBP laboratories.

Additional funds to support the MIEEP are also expected early in 2010. UCSF PRHE and UC Berkeley, in collaboration with CECBP staff, submitted a joint proposal to The California Wellness Foundation (TCWF) in August 2009, requesting \$250,000 over a two-year period. The additional resources will expand the pilot to include questionnaire administration, data analysis, and development of a best practices framework to communicate the results of chemical analyses to participants, even when the health implications may be uncertain or unknown. The results communication activity will be carried out in collaboration with researchers at UC Berkeley School of Public Health (SPH) (see Results Communication below).

3. Collaboration with the California Environmental Health Tracking Program (CEHTP)

In accordance with H&SC Section 105444(c), CECBP is working with CEHTP on community studies in Tulare and Imperial Counties. In the Tulare County study*, urine samples were collected in 2009 from community residents during pesticide application periods. The samples will be analyzed by CDPH's Environmental Health Laboratory (EHL) in 2010 for chlorpyrifos, a widely used pesticide that was recommended as a priority chemical for California by the SGP.

The Imperial County study is a community assessment of perchlorate and heavy metal exposure from drinking water, soil, and locally grown produce. Perchlorate is a component of rocket fuel that can affect the proper functioning of the thyroid gland, which plays a critical role in normal growth and development (particularly of the nervous system), as well as in the maintenance of health. This chemical has also been recommended as a priority for California by the SGP. The Colorado River, which is the primary source of irrigation and drinking water for the Imperial Valley, is contaminated with perchlorate due to ongoing runoff from a now-closed facility in Nevada. Exposure to perchlorate is potentially important not just in Imperial Valley, but in the rest of the

country, as the Valley produces much of the nation's winter produce. CEHTP staff collected urine specimens from Imperial Valley residents, as well as samples of drinking water and locally grown produce, in May 2009. Chemical analyses of water and produce are being conducted by laboratories at CDC, the University of Arizona, and CDPH's Food and Drug Laboratory Branch. CDPH laboratory staff is storing the urine samples, which will be analyzed in 2010 when the laboratory has developed, implemented, and validated methods to analyze perchlorate, arsenic, and several other metals.

The CEHTP provided approximately \$45,000 to the CDPH EHL for additional equipment and supplies to assist with sample collection, analysis, and storage for both the Imperial and Tulare County studies. CECBP staff will also work with the CEHTP to test methods for health communication and outreach regarding exposures by returning biomonitoring results in these two studies to participants who request them and by developing outreach and educational materials for participants, the general public, and health-care providers.

B. Results Communication

A distinctive feature of the CECBP is the legislative requirement that biomonitoring results be returned to study participants who request them, even though the health implications of these results may be scientifically uncertain (H&SC Section 105443). In 2008, CECBP began collaborating with Dr. Rachel Morello-Frosch, Associate Professor at the UC Berkeley SPH, in developing approaches to communicate biomonitoring results to study participants. In addition, CECBP is collaborating with Holly Brown-Williams, Director of Policy at Health Research for Action, UC Berkeley SPH, on health literacy and results communication.

Both Dr. Morello-Frosch and Ms. Brown-Williams participated in the planning process for the MIEEP and will contribute to the development of best practices for communicating results of chemical analyses to biomonitoring participants. As noted above, the biomonitoring projects conducted with CEHTP will also inform this effort. These collaborations will allow CECBP to develop best practices and appropriate materials for returning individual biomonitoring results to participants. Related to this work, OEHHA will identify levels of biomonitored chemicals in blood or urine that may be of health concern.

C. Plans for Statewide Survey

During FY 2007-08, to help plan the technical aspects and logistics of a five-year roll-out of a statewide biomonitoring program, CDPH entered into a contract with CDC's National Center for Health Statistics (NCHS). This contract is separate from the five-year CDC cooperative agreement described previously. This agreement was executed in part to comply with H&SC Section 105444(b), which directs the CECBP to "incorporate, as appropriate, the methods utilized by the [CDC] for the studies known collectively as the National Report on Human Exposure to Environmental Chemicals." The latter is based on biomonitoring of blood and urine samples collected from

participants in the NCHS-sponsored National Health and Nutrition Examination Survey (NHANES), which is designed to obtain health-related information from a representative sample of the nation's population. Data developed under NHANES are not intended to be representative of exposures in any given state, and the CDC will not release state-specific information.

NCHS staff assisted CDPH biomonitoring staff with developing four products:

1) A statistical model for selecting a valid representative sample of Californians to be recruited in two-year sampling cycles

The recommended sampling plan drafted by NCHS calls for recruiting and enrolling approximately 4,000 California residents per two-year cycle, assuming that laboratory costs and capacity would limit the CECBP to approximately 2,000 participants per year.

2) Concept of Operations

The Concept of Operations is a framework built around tasks required to carry out a large-scale state-wide representative biomonitoring survey based on the CDC model. These tasks include the logistics and procedures for participant recruitment and enrollment, data collection (e.g., questionnaires, physiological measurements), blood and urine specimen collection and shipping, reporting individual findings, and consultations/referrals for individuals with elevated levels of environmental contaminants with known clinical effects, such as mercury. Factors considered included workflow, timelines, and staff required to carry out defined tasks.

3) Staffing Plan

The Staffing Plan developed in conjunction with the Concept of Operations defined the various types of staff needed for participant recruitment and enrollment, as well as for operating temporary field clinics in selected sites around the state. At each site participants would have their blood and urine collected and some basic physiological measurements obtained, such as height, weight, and blood pressure.

4) Cost Model

NCHS also developed a Cost Model reflecting the activities, equipment, supplies, personnel, and travel costs needed to carry out all the phases of field data collection. The Cost Model was developed under the assumptions that a statewide biomonitoring survey would include a defined number of sampling sites per year, to be determined based on statistical and financial considerations, and that California could use this cost model as a framework to estimate and adjust costs for different numbers of survey sites.

These products were scalable in nature, and could be deployed for some regional and community-based studies as well as a statewide survey.

As originally conceived, the statewide biomonitoring survey would require a substantial information technology (IT) component. An IT system to support the CECBP would include automated processes and data management essential for handling a large volume of confidential health and exposure data obtained from participants throughout the state. The State Administrative Manual (Section 4819.35) requires preparation of a Feasibility Study Report (FSR) before IT funding can be approved. CECBP contracted with Shooting Star Solutions during FY 2007-08 to develop an FSR in conjunction with CDPH biomonitoring staff. The FSR, addressing the design, development, and implementation of the California Biomonitoring Information Technology System (CalBITS), was completed and approved by CDPH in June 2008 and submitted to the State Office of the Chief Information Officer (OCIO). However, the OCIO discontinued its review of the FSR because the Department of Finance did not support the project's use of the General Fund as its proposed funding source.

V. CECBP Laboratory Status

A. Laboratory Capacity and Capability

Laboratory analyses of environmental chemicals relevant to the CECBP are conducted by CDPH's EHL and DTSC's Environmental Chemistry Laboratory (ECL).

EHL provides environmental and clinical analytical services, as well as leadership in the development of laboratory methods, and serves as a reference laboratory for local and state public health agencies. It holds a Certificate of Compliance under the Clinical Laboratory Improvement Amendments (CLIA), which is a federal requirement for laboratories that conduct tests on human specimens and provide test results that could be used for diagnosis of disease or for other patient management decisions. Within the CECBP, EHL has primary responsibility for the development of novel, advanced, and improved methodologies for analysis of metals in blood and non-persistent chemicals in blood and urine. Non-persistent chemicals are rapidly metabolized and excreted, and include, for instance, many organophosphate insecticides and some plasticizers such as phthalates. In contrast, persistent chemicals, including chlorine-containing pesticides such as DDT, can remain in the environment, animals, and people for months to years.

CECBP funding has allowed EHL to procure and install one each of the following large instruments:

- High Resolution Gas Chromatograph-Mass Spectrometer (HR-GC/MS)
- High Pressure Liquid Chromatograph-Tandem Mass Spectrometer (HPLC/MS-MS)
- Inductively Coupled Plasma-Mass spectrometer (ICP/MS)
- Gilson 215 Liquid handler (for automating sample processing).

ECL serves as California's reference laboratory for analysis of toxic chemicals in the environment and consumer products. Although ECL collaborates with many researchers to measure persistent chemicals, the laboratory does not report individual results to study subjects and is not presently CLIA-certified. However, ECL staff and management are currently preparing an application for CLIA certification. Within the CECBP, 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).

CECBP funding has allowed ECL staff to procure and install an HR-GC/MS and an HPLC/MS-MS, as well as auxiliary equipment to be used for sample preparation and extraction.

With existing budgetary resources, both laboratories have hired initial staff to install and operate the new laboratory instruments. In consideration of priorities outlined by CECBP's Scientific Guidance Panel, staff has focused on developing methods, standard operating procedures, and quality assurance and quality control measures for the chemicals listed in Table 2. In 2010, both laboratories will begin analyses of samples collected through the CEHTP and archived biospecimens collected by university researchers (see below).

Current resource constraints limit both the numbers of analyses that can be run and the total number of chemicals that can be analyzed, since both are dependent on staffing, equipment, and availability of consumable supplies, such as test reagents. For example, EHL staff must divide access time for their one HPLC/MS-MS between phthalate and pesticide tests. Furthermore, ECL is able to conduct analyses on only one chemical class (e.g., PFCs or PBDEs and other flame retardants), as they have only two CECBP-funded staff. However, supplemental resources acquired through the CDC cooperative agreement (and potentially other sources) will allow for the hiring of more staff and the purchase of additional equipment and supplies, expanding the laboratories' capacity to conduct more analyses of a larger number of chemicals. Chemicals under consideration for analytical methods development include additional pesticides and metals, perchlorate, bisphenol A, and cyclosiloxanes (see Section III.B.).

Table 2. CECBP laboratory instruments and analytical methods*

Laboratory	Target Chemicals	Biological Specimen	Instrument	Date Method Ready
CDPH/ EHL	Metals (lead, mercury, cadmium)	Whole blood	ICP-MS	12/09
CDPH/ EHL	Phthalates (plasticizers)	Urine	HPLC/MS-MS**	12/09
CDPH/ EHL	3,5,6 Trichloropyridinol (a metabolite of chlorpyrifos, an organophosphate pesticide)	Urine	HPLC/MS-MS**	9/09
CDPH/ EHL	3-Phenoxybenzoic acid (a pyrethroid pesticide metabolite)	Urine	HPLC/MS-MS**	12/09
CDPH/ EHL	3-hydroxyphenanthrene (a polycyclic aromatic hydrocarbon)	Urine	HRGC/MS	12/09
CDPH/ EHL	Creatinine (for standardizing urinary chemical analysis)	Urine	plate reader	12/09
DTSC/ECL	Perfluorinated chemicals (PFCs)	Serum	HPLC/MS-MS	12/09
DTSC/ECL	Polybrominated diphenyl ethers (PBDEs and other brominated flame retardants)	Serum	HRGC/MS	12/09

* acronyms used in this table are defined in the text and in Appendix G

** shared machine for pesticide and phthalate analyses

The CECBP laboratories have executed a Memorandum of Understanding (MOU) with the Division of Laboratory Sciences (DLS), part of CDC's NCEH. Under the terms of the MOU, DLS will train CECBP laboratory staff in analytical methods and biospecimen collection, processing, storage, and shipping procedures, and will assist with proficiency testing to evaluate the quality of biomonitoring measurements. Additionally, DLS committed to analyze biological specimens from up to 500 participants (or mother-infant pairs) on a one-time basis, which would include analyses of up to ten chemical classes (each of which contains multiple chemicals), and to analyze samples from up to 200 participants for a single chemical. CECBP staff plan to build on the results of the pilot MIEEP by applying for external funding to support a 500-person paired maternal-infant exposure investigation.

B. Laboratory Fellowships

The CECBP laboratories applied for and were awarded two fellowships by the Association of Public Health Laboratories (APHL). Each Fellow has a Ph.D. in chemistry. The first APHL Environmental Fellow joined ECL in October 2008 and his fellowship was renewed to June 2010. He is working alongside ECL staff to develop analytical methods for BPA and several newer bromine-containing flame retardants in serum.

The other APHL Environmental Fellow joined EHL in February 2009 and is developing analytical methods for the determination of urinary phthalate metabolites. Her fellowship is scheduled to end in June 2010, but EHL is applying for an additional extension.

C. Instrument and Analytical Methods Training

CECBP laboratory staff received initial training on operation and maintenance of the newly installed instruments by the equipment vendors in early 2009 and advanced training in the summer after having had several months' experience in basic operations.

Through the MOU with CDC's DLS, CECBP staff attended CDC trainings in Atlanta. Four CDPH EHL staff received training in May 2009 on analytical methods for several CECBP priority chemicals (i.e., the metabolites of organophosphate pesticides, phthalate metabolites, BPA and hydroxylated polycyclic aromatic hydrocarbons (hydroxy-PAH)). In June 2009, three DTSC ECL staff received training focused on the analysis of persistent pollutants, including bromine-containing flame retardants and PFCs.

D. Analytical Methods Development

ECL staff members are adapting their current methods for measuring persistent environmental pollutants to match the CDC methods, using their new instruments. They are also applying the CDC methodology (with some necessary adaptations) for measuring PFCs.

EHL staff have adapted and validated two analytical methods for urine specimens: heavy metals and trichloro-2-pyridinol (TCP), a metabolite of the pesticide chlorpyrifos. Methods for hydroxy-PAHs, phthalate metabolites, and pyrethroid metabolites will be developed by December 2009. EHL is developing capacity to test for creatinine in urine and expects to have this method ready by December 2009. Creatinine is a normal product of human muscle metabolism that is excreted in urine, and needs to be measured in all urinary tests of environmental chemicals to standardize the results based on how dilute or concentrated the urine is.

E. Anticipated Analyses of Archived Biospecimens

In 2010, ECL will analyze PBDEs in archived serum samples collected by Columbia University researchers during 2005-2008 from California men. These biospecimens were collected as part of a Columbia University project examining whether environmental agents play a role in declining sperm counts in men. The Columbia researchers will investigate associations between major PBDEs and male reproduction.

EHL will analyze archived biospecimens from:

1. Tulare County for a metabolite of chlorpyrifos, an organophosphate pesticide;
2. UC Davis Childhood Autism Risks from Genetics and the Environment (CHARGE) study for phthalate metabolites and a chlorpyrifos metabolite. 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.
3. UC Berkeley Center for the Health Assessment of Mothers and Children of Salinas (CHAMACOS) for phthalate metabolites. CHAMACOS is a study examining environmental exposures and the health of low-income children from birth to five years of age in the Salinas Valley. EHL will also perform quality control studies to ensure the samples were not contaminated during collection or processing.

VI. Public Participation Activities

H&SC Section 105451 directs the CECBP 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.”

Initial public outreach activities in 2007 included setting up a CECBP listserv to facilitate electronic communication, a dedicated e-mail address, and a website. As of August 2009, the listserv had approximately 500 active subscribers. The CECBP website (<http://www.oehha.ca.gov/multimedia/biomon/index.html>), which is hosted and maintained by OEHHA, provides general information about the CECBP, including answers to frequently asked questions. In order to support public participation in SGP meetings and other CECBP activities, new materials are regularly added to the website, including meeting agendas, background documents, and presentations. While most of the website is in English, some basic program information is available in Spanish. The website was substantially reorganized in 2009 to improve accessibility. Future priorities include: (1) structured analysis of the CECBP website to improve its usability; (2) based on this analysis, development of new materials that address the need for easy-to-understand explanations of biomonitoring and the activities and findings of

CECBP; (3) translation of website materials into multiple languages; and (4) improved access to materials through website design modifications.

In order to build awareness of CECBP and engage potential stakeholders, CECBP staff held public workshops and teleconferences during April and May 2008. These forums provided information and answers to questions about biomonitoring and CECBP, and gathered public input regarding chemicals that should be priorities for biomonitoring. Three workshops were held, one each in Northern, Central, and Southern California, in which a total of 71 people participated. Simultaneous interpretation for Spanish-speaking audiences was offered for each workshop, but was requested at only one. Three publicly noticed teleconferences, with individuals participating from a total of 32 phone lines, addressed the same topics as the workshops and enabled participation from members of the public throughout the state. CECBP staff also designed and implemented a web-based survey (available in both English and Spanish) to gather suggestions on selecting chemicals for the Program. Over 300 individuals participated in the survey, including people from non-governmental and community-based organizations, state and local government agencies, universities and businesses, as well as other interested state residents. Preliminary results of these activities were presented to the SGP in June 2008. The final report summarizing these public participation activities and results is included in Appendix E and is also available online at <http://oehha.ca.gov/multimedia/biomon/pdf/PublicParticipationreport021909.pdf>. Appendices to the report on public participation activities can be found at <http://www.oehha.ca.gov/multimedia/biomon/reports.html#state>. CECBP also queried California state staff in a variety of programs in several different agencies and departments to elicit information on which chemicals these staff considered important for biomonitoring. The report summarizing state staff input was presented to the SGP in June 2008 and is included as Appendix F. It is also available online at <http://oehha.ca.gov/multimedia/biomon/pdf/StateGovReport021909.pdf>. Both the public participation results and the state government survey have informed the SGP deliberations on designated and priority chemicals.

CECBP staff has also developed a draft public participation strategy and plan, embodying the directive of H&SC Section 105451 “to establish the framework for integrating public participation.” The strategy and plan will create additional opportunities for stakeholders to help shape the program’s future, and include goals and objectives to guide CECBP efforts, as well as specific activities to be carried out as resources allow. The plan calls for more outreach to identify individuals and institutions interested in biomonitoring activities in California, including community-based and other non-governmental organizations; local, regional, and statewide public health professionals; members of the business community; and the general public. Additional activities to educate the public about sample collection and to share biomonitoring results are also included. Staff anticipates releasing the draft public participation strategy and plan for public comment in early 2010.

Under the CDC cooperative agreement, a field investigations coordinator was hired in October 2009 to conduct public participation activities for targeted biomonitoring investigations. These activities will include identifying stakeholders and conducting

needs assessments. Resources are also earmarked to support activities designed to enhance stakeholder participation in the CECBP. For instance, a basic informational brochure to help recruit participants and to introduce the topic of biomonitoring will be created and tested in focus groups. Key documents will be translated into languages other than English to improve CECBP's connections with California's diverse population.

VII. Conclusions and Recommendations

During its first two years, CECBP has made significant progress in planning for statewide and community biomonitoring surveys, supporting the SGP, identifying designated and priority chemicals, building laboratory capability and capacity to analyze selected priority environmental chemicals, and providing opportunities for public participation. Data from the analysis of a limited number of biospecimens collected by other researchers will also be available in 2010.

With the additional resources available through a newly acquired federal cooperative agreement, CECBP laboratories will continue to build laboratory capability and capacity to analyze priority chemicals. Staff will also carry out targeted biomonitoring investigations, including a paired maternal-infant exposure investigation, and explore collaborations with other researchers. Public participation activities, especially those involving biomonitoring investigations, will include efforts to make information about the CECBP more accessible.

The biggest challenge facing CECBP is to identify a stable, long-term source of funding that will enable the program to implement SB 1379's mandate for a statewide biomonitoring program that will provide policymakers and the public with information on the levels of environmental chemicals in a representative sample of California residents. Until this funding source is identified, CECBP staff will continue to focus on securing grants, cooperative agreements, and other external funding to support smaller-scale biomonitoring studies. Such studies have significant value in themselves and, properly designed, their results can be generalized to larger populations, which can inform future policy decisions about some exposures to environmental chemicals in California. However, community studies cannot provide the breadth of information about exposures in California's diverse population that can be obtained with statewide surveys. The latter are needed to more thoroughly evaluate the effectiveness of California's environmental regulatory programs and make the most informed decisions on steps to protect Californians from environmental chemicals that pose the greatest hazards.

Recommendations from the SGP for improving the CECBP (please refer to Appendix G, a letter from the SGP Chair):

1. Identify and secure a stable long-term funding mechanism to allow full CECBP implementation of statewide and community based biomonitoring surveys in accordance with legislative mandates.

2. Continue to pursue external funding opportunities and collaborations with other researchers that leverage existing resources to:
 - Carry out various program components mandated by SB 1379,
 - Obtain biomonitoring data to assess Californians' exposure to chemicals, and
 - Develop targeted biomonitoring studies of individuals who are exposed to priority chemicals occupationally.
3. Conduct activities specified in the CDC cooperative agreement to increase laboratory capability and capacity, resulting in an increase in both the number of tests and types of chemicals that CECBP staff can measure.
4. Conduct outreach efforts to identify and engage additional CECBP stakeholders and encourage their involvement in program development and implementation.
5. Continue to maintain and expand CECBP electronic resources, including: website improvements (e.g., easy-to-understand materials, translation of more materials into multiple languages, and improved accessibility); internet broadcasting or audio-casting of all SGP meetings; increased numbers of listserv subscribers; and more surveys of subscribers to identify program-related needs and concerns.
6. Continue to meet with the SGP three times per year to provide Panel members with information and the opportunity to make recommendations to CECBP, as well as provide the public an opportunity to comment on program activities.
7. Continue to research and develop materials to support the SGP in selecting designated and priority chemicals to include in the CECBP.
8. Continue to develop results communication methods and materials for individual participants, health-care providers, and interested groups.
9. Identify levels of biomonitored chemicals in blood or urine that may be of health concern.