

IMPLEMENTATION OF THE CALIFORNIA ENVIRONMENTAL
CONTAMINANT BIOMONITORING PROGRAM

**Executive Summary 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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Executive Summary

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). 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 provided by a distinguished Scientific Guidance Panel (SGP) and substantial opportunities for input by the public. The CECBP is the first legislatively mandated ongoing state biomonitoring program in the country.

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 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. Under SB 1379, the program is structured to identify and prioritize for analysis those chemicals of greatest potential public health concern to California residents. SB 1379 requires the program to submit progress reports every two years to the Legislature, beginning in January 2010. This document is the first of these reports.

Program Structure and Resources

CECBP is collaboratively administered by staff in three state departments. Responsibilities are broadly divided in the following manner:

- 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) processing, storage and analysis of blood and urine samples for specified priority chemicals, including metals and chemicals that are not biologically persistent; (4) communication of test results to participants who request them; (5) data analysis; (6) generation of reports to the Legislature; and (7) dissemination of information to the public.
- OEHHA has primary responsibility for: (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.
- DTSC has primary responsibility for analysis of blood samples for biologically persistent priority chemicals, such as flame retardants; and data analysis.

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.

Baseline annual program funding for all three CECBP departments from FY 2007-08 to the present is \$1.9 million. In FY 2008-09, the Legislature transferred CECBP's funding from the General Fund to the Toxic Substances Control Account (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. TSCA annual revenues are not sufficient to cover annual expenditures. 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).

The CECBP was envisioned in SB 1379 to include a large-scale statewide survey, in which the program would measure levels of environmental chemicals in the blood, urine and possibly other biological specimens obtained from a representative sample of

California residents. However, because program funding has remained at baseline levels, implementation of the statewide program has had to be suspended. Nevertheless, considerable progress has been made on other aspects of program implementation, as described below.

CECBP staff has successfully sought supplemental extramural support. In collaboration with the nonprofit Sequoia Foundation, the CECBP submitted an application to the U.S. Centers for Disease Control and Prevention (CDC) in response to a competitive Request for Applications. CDC awarded California, New York and Washington states 5-year cooperative agreements to increase state biomonitoring laboratory capability and capacity. The CDC has indicated that this funding is to be used to supplement, not replace, existing state biomonitoring program support. The cooperative agreement's first year of funding (\$2.6 million) began on September 1, 2009. Some of the CDC cooperative agreement resources will be used to support smaller-scale community-based studies. CECBP staff members are seeking funding from other organizations to supplement both state and CDC resources.

Scientific Guidance Panel and Chemical Selection

A nine-member Scientific Guidance Panel (SGP) appointed by the Governor and the Legislature provides scientific peer review for the CECBP. As required by SB 1379, the SGP has met three times per year for a total of seven meetings since the program began. These meetings provide opportunities for CECBP staff to update the SGP and the public on program activities, request feedback and recommendations from the SGP members, and receive public comment. The SGP has played a critical role in identifying and recommending for biomonitoring those priority chemicals of greatest potential public health importance for California's population.

Selection of chemicals that may be included in CECBP surveys involves a two-step process. Only substances identified as "designated chemicals" may be biomonitored under SB 1379. These are defined as chemicals included in CDC national exposure studies or added by the SGP according to a process described in the legislation. From the designated chemicals list, the SGP recommends "priority chemicals." Examples of priority chemicals recommended by the Panel include brominated and chlorinated compounds used as flame retardants, mercury and other heavy metals, perchlorate, bisphenol A, some organophosphate and pyrethroid pesticides, some perfluorinated chemicals, and some phthalates.

Study and Sample Design

CECBP disseminated a request to researchers throughout the United States to identify those who had recently collected blood or urine specimens from Californian residents. Researchers at three universities will be providing CECBP laboratories specimens to be analyzed for selected priority chemicals starting in 2010. This information will assist CECBP to determine the types and levels of environmental chemicals present in Californians. Additionally, under the CDC cooperative agreement, CECBP and staff in the University of California (UC) San Francisco Program on Reproductive Health and

the Environment (PRHE) have designed a pilot project to assess chemical exposures in 100 pregnant women and infants in San Francisco. Finally, CECBP is also working with the California Environmental Health Tracking Program (CEHTP) on two community biomonitoring studies in Tulare and Imperial Counties.

To comply with the mandate of SB 1379, CECBP staff initially developed a five-year plan, in consultation with the CDC National Center for Health Statistics, to implement a statewide biomonitoring program, which was to be modeled after an ongoing federal government survey known as the National Health and Nutrition Examination Survey (NHANES). Under a contract initiated in 2007, the CDC National Center for Health Statistics worked with CECBP staff to develop a program plan for a statewide survey in California that would result in biomonitoring participants from 48 counties over a six-year period beginning in 2011. However, as noted, subsequent funding limitations have limited further development of the statewide survey.

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 uncertain or unknown. CECBP is collaborating with researchers at UC Berkeley to develop best practices and materials for returning individual test results to participants. CECBP staff is also beginning work to identify levels of biomonitored chemicals in blood or urine that may be of health concern.

Laboratory Status

CDPH's Environmental Health Laboratory (EHL) and DTSC's Environmental Chemistry Laboratory (ECL) conduct laboratory analyses of environmental chemicals in biological specimens. EHL has primary responsibility for the development of methods for analysis of toxic metals in blood and non-persistent chemical contaminants in blood and urine. ECL primarily focuses on biologically persistent chemicals in blood. CECBP funding has allowed both EHL and ECL to hire initial staff and to procure and install state-of-the-art analytical equipment. The laboratories have focused on developing testing methods, instrument standard operating procedures, and quality assurance measures for chemicals to be analyzed. In the coming year, both laboratories will analyze blood and urine samples from California residents collected through the CEHTP and university researchers. Although baseline funding limits the number of tests that can be completed, as well as the number of chemicals that can be analyzed, supplemental funding through the CDC cooperative agreement will allow for substantial augmentation of laboratory capacity.

The CECBP laboratories have also executed a Memorandum of Understanding (MOU) with the Division of Laboratory Sciences (DLS) of CDC's National Center for Environmental Health. Under the MOU, DLS will train CECBP laboratory staff and assist CECBP laboratories with quality assurance and quality control protocols.

Public Participation Activities

Initial activities to promote public participation included setting up a CECBP listserv, a dedicated email address, and a website. CECBP staff conducted public workshops in three regions of California and several statewide teleconferences in March and April 2008, to introduce the program to the public and stakeholders and to solicit input on program implementation. An online survey was also conducted in 2008 to obtain additional input. Members of public have participated in SGP meetings, which have been webcast when possible to expand access. CECBP staff has also developed a draft public participation strategy and plan, embodying the legislative directive “to establish the framework for integrating public participation.” The strategy and plan include goals and objectives to guide CECBP efforts, as well as specific activities to be carried out as resources allow, and will create additional opportunities for stakeholders to help shape the program’s future. Future activities designed to meet SB 1379’s public participation objectives include expanding electronic resources and generating opportunities to increase the number and diversity of stakeholders engaged in CECBP implementation.

Conclusions and Recommendations

With currently available baseline resources, CECBP has made significant progress in planning for community biomonitoring surveys, identifying designated and priority chemicals, building laboratory capability and capacity to analyze selected environmental chemicals, and providing opportunities for public participation. A recently awarded CDC cooperative agreement will allow CECBP laboratories to continue building capability and capacity.

Although staff originally estimated that the CECBP would be fully implemented over five years (by 2011), insufficient resources have limited the full implementation of a statewide sampling program representative of California’s diverse population. Consequently, the CECBP has modified its implementation plans and activities to focus on smaller community and pilot studies. Additionally, CECBP has leveraged its existing baseline state resources to obtain external funding and to collaborate with other programs and researchers.

The CECBP’s external Scientific Guidance Panel has commended staff for program accomplishments in light of limited resources and strongly supports the continuation of current efforts. In addition, the SGP has recommended that worker groups be included in targeted biomonitoring studies. Finally, the SGP recommends that stable long-term funding be identified to allow implementation of both statewide and community biomonitoring studies, as envisioned and mandated by the Legislature in SB 1379.