SB-1379 Biomonitoring. (2005-2006)

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Senate Bill No. 1379

CHAPTER 599

An act to add Chapter 8 (commencing with Section 105440) to Part 5 of Division 103 of the Health and Safety Code, relating to public health.

[Approved by Governor September 29, 2006. Filed with Secretary of State September 29, 2006.]

LEGISLATIVE COUNSEL'S DIGEST

SB 1379, Perata. Biomonitoring.

Existing law establishes various programs for the protection of the public from exposure to toxins, including, but not limited to, the Childhood Lead Poisoning Prevention Act, administered by the State Department of Health Services, which imposes a fee upon manufacturers or persons who are responsible for lead contamination and applies the proceeds of the fee to reduction or elimination of the harm caused by the lead contamination.

This bill would require the department in collaboration with the California Environmental Protection Agency to establish the California Environmental Contaminant Biomonitoring Program to monitor the presence and concentration of designated chemicals, as defined, in Californians.

This bill would require the department and the agency to establish a Scientific Guidance Panel to assist the department and the agency. The bill would require the department to provide public access to information, and to report to the Legislature and the public.

Vote: majority Appropriation: no Fiscal Committee: yes Local Program: no

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. The Legislature finds and declares all of the following:

(a) An estimated 100,000 chemicals are registered for use today in the United States. Another 2,000 chemicals are added each year. Some toxicological screening data exists for only 7 to 10 percent of these chemicals. More than 90 percent of these chemicals have never been tested for their effects on human health. Large numbers of these chemicals are found in cosmetics, personal care products, pesticides, food dyes, cleaning products, fuels, and plastics. Because of their ubiquity in modern life, Californians are commonly exposed to multiple chemicals every day. Many of these chemicals persist in the environment, and accumulate and remain in body fat, and have been shown to be toxic.

(b) Biomonitoring studies have scientifically demonstrated that human exposure to a multitude of chemicals is widespread. The federal Centers for Disease Control and Prevention has documented the presence of 148 environmental chemicals in the blood and urine of Americans of all ages and races.

(c) Biomonitoring studies will provide data that will help California scientists, researchers, public health personnel, and community members explore linkages between chemical exposures and health.

(d) Biomonitoring data supports public health by establishing trends in chemical exposures, validating modeling and survey methods, supporting epidemiological studies, identifying highly exposed communities, addressing the data gaps between chemical exposures and specific health outcomes, informing health responses to unanticipated emergency exposures, assessing the effectiveness of current regulations, and helping to set priorities for reform.

(e) In September 2001, the Legislature passed Senate Bill 702 (Chapter 538, Statutes of 2001), making California the first state in the nation to begin planning a statewide environmental health tracking network for chronic diseases and environmental hazards and exposures. To help implement the program, the Senate Bill 702 Expert Working Group has recommended the establishment of a statewide biomonitoring program.

(f) In September 2003, the Legislature passed Assembly Bill 1360 (Chapter 664, Statutes of 2003), that requires the development and use in California of a comprehensive system of environmental measurements known as environmental indicators. The basis for the bill was the April 2002 report, "Environmental Protection Indicators for California," by the California Environmental Protection Agency and the Resources Agency. This report identifies biomonitoring as part of an overall system of environmental indicators that California should develop to guide policy and budgetary decisions.

(g) The Legislature, therefore, finds and declares 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. A statewide and community-based biomonitoring program will expand biomedical, epidemiological, and behavioral public health research. California, an established leader in health promotion, health policy, and health care delivery and response, should encourage and fund this research, which will contribute to the health and well-being of millions of people.

SEC. 2. Chapter 8 (commencing with Section 105440) is added to Part 5 of Division 103 of the Health and Safety Code, to read:

CHAPTER 8. California Environmental Contaminant Biomonitoring Program
Article 1. General

105440. (a) This chapter shall be known, and may be cited, as the California Environmental Contaminant Biomonitoring Program.

(b) For the purposes of this chapter, the following terms have the following meanings:

(1) "Agency" means the California Environmental Protection Agency.

(2) "Biomonitoring" means the process by which chemicals and their metabolites are identified and measured within different biological specimens.

(3) "Biological specimen" means a sample taken from a biophysical substance, that is reasonably available within a human body, for use as a medium to measure the presence and concentration of toxic chemicals.

(4) "Community" means geographically or nongeographically based populations that may participate in the community-based biomonitoring program. A "nongeographical community" includes, but is not limited to, populations that may share a common chemical exposure through similar occupations, populations experiencing a common health outcome that may be linked to chemical exposures, or populations that may experience similar chemical exposures because of comparable consumption, lifestyle, product use, or subpopulations that share ethnicity, age, or gender.

(5) "Department" means the State Department of Health Services.

(6) "Designated chemicals" means those chemicals that are known to, or strongly suspected of, adversely impacting human health or development, based upon scientific, peer-reviewed animal, human, or in vitro

studies, and consist of only those substances including chemical families or metabolites that are included in the federal Centers for Disease Control and Prevention studies that are known collectively as the National Reports on Human Exposure to Environmental Chemicals program and any substances as specified pursuant to subdivision (c) of Section 105449.

(7) "Director" means the Director of Health Services.

(8) "DTSC" means the Department of Toxic Substances Control within the agency.

(9) "Office" means the Office of Environmental Health Hazard Assessment within the agency.

(10) "Panel" means the Scientific Guidance Panel established pursuant to Article 2 (commencing with Section 105448).

(11) "Program" or "biomonitoring program" means the California Environmental Contaminant Biomonitoring Program, which shall be established and operated by the department, in collaboration with the agency, the office, and DTSC.

(12) "Secretary" means the Secretary of the California Environmental Protection Agency.

105441. The department, in collaboration with the agency, shall establish the California Environmental Contaminant Biomonitoring Program. The department is the lead entity for the program unless otherwise specified in this chapter. The program shall utilize biological specimens, as appropriate, to identify designated chemicals that are present in the bodies of Californians. Biomonitoring shall utilize scientifically based statewide surveys. Additional community-based surveys shall be contingent on funding and shall be statistically valid and scientifically based. Biomonitoring shall take place on a strictly voluntary and confidential basis. Results reported pursuant to this chapter shall not disclose individual confidential information of participants. Appropriate biological specimens shall be used to monitor and assess the presence and concentration of designated chemicals. Biological specimens shall be analyzed by laboratories operated by the department, DTSC, or their contractors.

105443. (a) All participants shall be evaluated for the presence of designated chemicals as a component of the biomonitoring process. Participants shall be provided with information and fact sheets about the program's activities and its findings. Individual participants may request and shall receive their complete results. Any results provided to participants shall be subject to the Institutional Review Board protocols and guidelines. When either physiological or chemical data obtained from a participant indicate a significant known health risk, program staff experienced in communicating biomonitoring results shall consult with the individual and recommend followup steps, as appropriate. Program administrators shall receive training in administering the program in an ethical, culturally sensitive, participatory, and community-based manner.

(b) Individuals selected to participate in the biomonitoring program shall reflect the age, economic, racial, and ethnic composition of the state. Other selection criteria may be applied, as appropriate, for studies of specific populations.

(c) Informational materials and outreach activities directed to program participants and communities shall, to the extent possible, be culturally appropriate and translated as needed. Educational materials shall be adapted to the biological specimens being used.

105444. (a) The program shall develop guidelines and model protocols that address the science and practice of biomonitoring to implement this chapter, including, but not limited to, study design, subject recruitment, and data collection and management, and that accomplish all of the following:

(1) Ensure confidentiality and informed consent.

(2) Communicate findings to participants, communities, and the general public.

(3) Emphasize all aspects of the program in a culturally sensitive manner.

(4) Serve as a guide for other biomonitoring programs supported by state funds.

(b) The program shall incorporate, as appropriate, the methods utilized by the federal Centers for Disease Control and Prevention for the studies known collectively as the National Report on Human Exposure to Environmental Chemicals.

(c) The program shall be implemented in collaboration with the California Environmental Health Tracking Program and the environmental indicators system maintained by the office pursuant to Section 71081 of the Public Resources Code.

(d) The department, office, and DTSC shall collaborate on the development of fact sheets and other informational and outreach materials for the biomonitoring program.

(e) The department, in collaboration with the office and DTSC, shall conduct statistical and epidemiological analyses of the biomonitoring results.

(f) Personal information as defined in Section 1798.3 of the Civil Code, shall not be shared without the written and informed consent of the individual to whom it pertains.

(g) No governmental agency or private person or entity shall discriminate against a person or community based upon the biomonitoring results.

Article 2. The Scientific Guidance Panel

105448. (a) In implementing the program, the department and the agency shall establish a Scientific Guidance Panel. The panel shall be composed of nine members, whose expertise shall encompass the disciplines of public health, epidemiology, biostatistics, environmental medicine, risk analysis, exposure assessment, developmental biology, laboratory sciences, bioethics, maternal and child health with a specialty in breastfeeding, and toxicology.

(b) The Governor shall appoint five members to the panel, the Senate Committee on Rules shall appoint two members, and the Speaker of the Assembly shall appoint two members. The appointments shall be made after soliciting recommendations of the Office of the President of the University of California.

(c) All members shall be appointed to the panel by September 1, 2007. Members shall be appointed for three-year terms, except that, with respect to the initial appointees each appointing power shall appoint one member for a one-year term and one member for a two-year term. Members may be reappointed for additional terms without limitation.

(d) The panel shall meet as often as it deems necessary, with consideration of available resources, but at a minimum, three times per year. The office shall be responsible for staffing and administration of the panel.

(e) The panel meetings shall be open to the public and be subject to the Bagley-Keene Open Meetings Act (Article 9 (commencing with Section 11120) of Part 1 of Division 3 of Title 2 of the Government Code).

(f) Members of the panel shall be reimbursed for travel and other necessary expenses incurred in the performance of their duties under this chapter, but shall not receive a salary or compensation.

105449. (a) The panel shall provide scientific peer review and make recommendations regarding the design and implementation of the program, including specific recommendations for chemicals that are priorities for biomonitoring in California, as specified in subdivisions (b) and (c), with the program retaining final decisionmaking authority.

(b) The panel shall recommend priority chemicals for inclusion in the program using the following criteria:

(1) The degree of potential exposure to the public or specific subgroups, including, but not limited to, occupational.

(2) The likelihood of a chemical being a carcinogen or toxicant based on peer-reviewed health data, the chemical structure, or the toxicology of chemically related compounds.

(3) The limits of laboratory detection for the chemical, including the ability to detect the chemical at low enough levels that could be expected in the general population.

(4) Other criteria that the panel may agree to.

(c) The panel may recommend additional designated chemicals not included in the CDC report, for inclusion in the program using the following criteria:

(1) Exposure or potential exposure to the public or specific subgroups.

(2) The known or suspected health effects resulting from some level of exposure based on peer-reviewed scientific studies.

(3) The need to assess the efficacy of public health actions to reduce exposure to a chemical.

(4) The availability of a biomonitoring analytical method with adequate accuracy, precision, sensitivity, specificity, and speed.

(5) The availability of adequate biospecimen samples.

(6) The incremental analytical cost to perform the biomonitoring analysis for the chemical.

105451. (a) As appropriate, the program shall utilize the principles of the agency's Environmental Justice Strategy and Environmental Justice Action Plan developed pursuant to Sections 71110 to 71113, inclusive, of the Public Resources Code, so that the activities of the panel and the implementation of the program provide opportunities for public participation and community capacity building with meaningful stakeholder input. This strategy and plan shall accord the highest respect and value to every individual and community by developing and conducting public health and environmental protection programs, policies, and activities in a manner that promotes equity and affords fair treatment, accessibility, and protection for all Californians, regardless of race, age, culture, income, or geographic location.

(b) (1) To carry out this section, the program shall develop a strategy and plan that are to be followed in the implementation of the program. This strategy and plan shall be used to establish the framework for integrating public participation in this program. The department may utilize models used by boards, departments, and offices at the agency for community outreach pursuant to this section.

(2) Public participation shall include, but need not be limited to, conducting stakeholder meetings and workshops to solicit relevant information, data, suggestions, and feedback for the development and implementation of the program.

Article 3. Fiscal Provisions

105453. Implementation of this chapter shall be contingent on a specific appropriation being provided for this purpose in the annual Budget Act or other measure.

Article 4. Reporting

105459. (a) By January 1, 2010, and every two years thereafter, the department, in collaboration with the agency, the office, 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.

(b) The department shall provide the public access to information which they are required to release pursuant to the California Public Records Act (Chapter 3.5 (commencing with Section 6250) of Division 7 of Title 1 of the Government Code).

(c) The department and the office shall disseminate biomonitoring findings to the general public via appropriate media, including governmental and other Web sites in a manner that is understandable to the average person.

(d) Any health and environmental exposure data made available to the general public shall be provided in a summary format to protect the confidentiality of program participants. The data shall be made available, after appropriate quality assurance and quality control, by July 1, 2010, and at least every two years thereafter.