MOVING TOWARD A GREEN CHEMICAL FUTURE

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I. INTRODUCTION

The U.S. government's current regulation of industrial chemicals is based on the presumption that these chemicals are innocent until they are proven to harm human health or the environment. This presumption is startling, especially when you consider:

- There are an estimated 80,000 chemicals registered for commercial use in the U.S.[1]
- Only a very small percentage of these chemicals have been tested for safety to human health.[2]
- An estimated 2,000 new chemicals are introduced each year, or an average of seven new chemicals each day.[3]

To date, California has relied on the federal government's failed regulatory system to protect its residents from industrial chemicals used in commerce. California has no regulatory framework for reviewing these chemicals prior to their introduction to the market and use in consumer products. Nor does the state have a comprehensive program for assessing the safety of those chemicals currently in use.

Last year, California Environmental Protection Agency Secretary Linda Adams launched the Green Chemistry Initiative to develop a comprehensive approach for dealing with hazardous chemicals. Over the past year, Environment California Research & Policy Center has participated in the initiative through stakeholder meetings, individual meetings with California Department of Toxic Substances Control Director Maureen Gorsen and her staff, the submission of comments describing our core principles for comprehensive chemicals policy reform, and extensive work with partnering organizations in the coalition Californians for a Healthy and Green Economy (CHANGE), including the submission of comments and responses to questions on the Green Chemistry Initiative blog and the development of chemicals policy options and a framework for implementing reform measures.

The inception of this report stemmed from a desire to better understand the types of policies currently in place or being proposed to address the problems with chemical oversight in the United States and to provide useful information to others currently engaged in efforts to reform existing law. Accordingly, this report evaluates existing and proposed chemicals policy frameworks in the context of California, using Environment California Research & Policy Center's core principles of a comprehensive chemicals policy as the measure for evaluation. These core principles reflect a chemicals policy paradigm that emphasizes a hazard-based approach for assessing chemicals, largely reflecting the collective wisdom of environmental health and justice advocates working on chemicals policy reform through CHANGE.

The intended audience includes our coalition partners, policymakers, and those interested in better understanding the current models for reform and some of the relevant policies within the state that collectively comprise the patchwork of laws and regulations governing industrial chemicals. This report limits the discussion of chemicals policy to the control of industrial chemicals, which excludes cosmetics, pharmaceuticals, pesticides, food, food additives, tobacco, and nuclear materials, consistent with those substances covered by the federal Toxic Substances Control Act (TSCA).

In Environment California Research & Policy Center's view, the fundamental goal of a comprehensive chemicals policy is to create a chemicals management program that provides for the collection and evaluation of health and environmental impacts data, prohibits or restricts the use of chemicals known to cause harm or for which data do not exist to make such a determination, and incorporates substitution policies that drive businesses to use safer chemicals or practices. Such a scheme must be transparent at every step, enabling businesses to make informed decisions about the chemicals they use and providing the public with understandable information about potential toxic threats and safer choices in the marketplace.

II. CORE PRINCIPLES FOR CHEMICALS POLICY REFORM

Environment California Research & Policy Center views the following principles as central to chemicals policy reform and, specifically, to the success of California's Green Chemistry Initiative:

1. Decisions affecting human health and the environment should be based on the intrinsic hazards of a chemical and a new approach to toxicity testing.
California should adopt a hazard-based approach to chemicals policy whereby policy actions to reduce or eliminate a chemical's use should be triggered by a chemical's intrinsic hazards, including a chemical's toxic, persistent, or bioaccumulative qualities and a chemical's ability to cause biological changes that are likely to lead to diseases. Based on a chemical's intrinsic hazards, the state should determine any necessary immediate action to be taken, including removing a chemical from the market. Further, information on mutagenicity, genetic toxicity, reproductive effects, developmental toxicity, carcinogenicity, immunological effects, neurological and neurodevelopmental effects, effects on organs, respiratory effects, epigenetic effects, and endocrine disruption should guide decisions about how and whether chemicals should be used in society. Where there is uncertainty in the evidence, policies should err on the side of protecting health and the environment.

Currently, most decisions regarding chemicals are based on a complicated, time-consuming, and resource-intensive process that attempts to assess risk through a calculation of exposure and potential harm, rather than err on the side of protecting health and preventing disease by avoiding chemical use where there is evidence of potential harm. This means that even when there are good data on the dangers of chemicals, these substances are still allowed on the market with regulators simply trying to "manage" the risk by finding "safe" levels. Such a process typically relies on inadequate hazard information and an assessment of exposure, which only provides a snapshot into the particular time the chemical is being evaluated. Most often, risk assessments are conducted with incomplete information on the range of potential health and environmental impacts with which we are concerned. Moreover, because the uses of chemicals and exposures to chemicals can and do change, the fundamental assumptions about exposures relied upon to ultimately assess and manage risk lack long term validity with respect to the protection of human health and the environment.

California must invest in the development of new testing methods to assess and characterize chemicals. Current methods are outdated; fail to incorporate key concepts, such as the timing of exposure, cumulative exposures, synergistic effects of chemicals, and low-dose impacts; and do not address all of the important hazard traits, especially those of concern for women and children. Decisions about chemicals should be based on a new approach that accounts for these and other emerging concepts.

2. Chemical manufacturers should prove their products are safe.
For existing chemicals, chemical manufacturers should be required to prove their products are safe in order to allow their continued manufacture and use. By 2010, chemical manufacturers should be required to provide to the appropriate governmental body all hazard and safety information for existing chemicals for which little or inadequate data are available. Required data should include detailed information on the physical properties and intrinsic hazards of a chemical as described above. For new chemicals, such information should be required before they are permitted to be manufactured.

In addition, the reliability and adequacy of the information must be validated. Through either an independent third party without a conflict of interest or the recipient governmental body, information provided by chemical manufacturers must be evaluated for its adequacy in meeting the requirements and reliability as scientific evidence.

3. Hazardous chemicals and chemicals with inadequate safety data should be phased out.
If a chemical is known to pose a hazard to human health or the environment and a safer alternative exists, it should be tracked for immediate phase out. If a chemical is known to pose a hazard to human health or the environment and a safe alternative *does not* exist, its use and potential exposures should be minimized and a timeline for its phase out should be established.

If a chemical has not been adequately evaluated for potential hazards and a safer alternative exists, it should be tracked for immediate phase out. If a chemical has not been adequately evaluated for potential hazards and a safer alternative *does not* exist, its use and potential exposures should be minimized and a timeline for its phase out should be established.

4. Industry should bear the costs associated with their chemical production or use.
Manufacturers and users of chemicals should be held responsible legally and financially for the costs and consequences of producing and/or using hazardous or potentially hazardous chemicals. Manufacturers should bear the financial burden of testing chemicals for safety and making the data available to potential users. Users should pay fees in order to use a hazardous chemical in advance of an eventual phase out of the chemical. Users of hazardous chemicals incorporating them into consumer products should be required to take back their products from consumers to ensure proper disposal. With respect to past behavior, those responsible for contaminating California's environment and households should bear the costs of clean up.

5. Safer alternatives to hazardous chemicals should be required.
With the mandated phase out of hazardous chemicals, safer alternatives should be required. In addition to chemical-for-chemical substitutions, chemical users should consider changing their manufacturing processes, selecting alternative materials, and redesigning their products. Safer alternatives must be evaluated for their intrinsic hazards, as described above.

6. The public has a right to know about chemicals in use and participate in decisions affecting the impact of these chemicals on their communities.
The public has a right to know about chemicals currently on the market, including their specific uses, potential hazards to health and the environment, and potential exposures. Such information should never be considered confidential business information. California should create an easily understood matrix of all chemicals currently in use with information on their hazard traits for use by downstream users, consumers, and other interested parties. Such a matrix would: 1) identify missing data, 2) enable businesses and consumers to compare the safety of chemicals, and 3) support the promotion of and create demand for safer alternatives.

Right to know laws also should include mandatory labeling on consumer products and disclosure regarding manufacturing processes indicating the presence of chemicals that are or may be hazardous. Until health and safety data are available for a particular chemical, there should be mandatory labeling for consumer products indicating the presence of chemicals that have not been tested for their impact on human health.

The public also has a right to participate in decisions about chemicals that could affect public health or the environment.

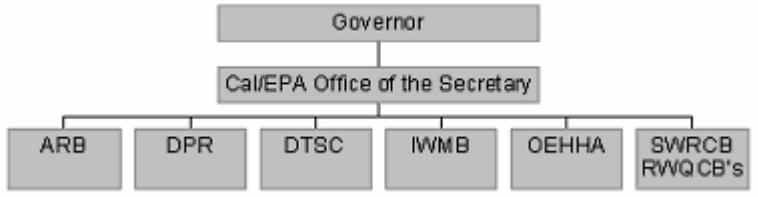
III. PROVIDING THE CALIFORNIA CONTEXT

The principles described above represent a significant shift in the rationale underlying current chemical regulation and the way such regulation is carried out in California. Current California law attempts to address some of the hazards associated with chemicals, but for the most part, the California Environmental Protection Agency and its boards, departments, and office lack the appropriate authority to focus on preventing harm from chemical exposures rather than mitigating harm already done. This section provides the California context for the eventual adoption of a comprehensive chemicals policy. The federal government's failure to adequately and effectively protect the environment and human health from hazardous chemicals necessitates that California take the lead in implementing health-protective policies that seek to prevent harm.

A. California's Environmental Oversight

In 1991, California's environmental protection authority was unified in a single Cabinet level agency—the California Environmental Protection Agency (CalEPA). This brought the Air Resources Board (ARB), State Water Resources Control Board (SWRCB), Regional Water Quality Control Boards (RWQCBs), and the Integrated Waste Management Board (IWMB) under an umbrella agency with the newly created Department of Toxic Substances Control (DTSC),[i] Office of Environmental Health Hazard Assessment (OEHHA),[ii] and Department of Pesticide Regulation (DPR).[iii,4] See Figure 1.

Figure 1



The Secretary of CalEPA does not direct the policies and decisions of these six boards, departments, and office (BDOs) on a day-to-day basis. As an officer of the Governor's Cabinet with statutory responsibility to coordinate and supervise the overall performance of CalEPA, the Secretary provides the vision and leadership that ensure the efforts of the BDOs align with the goals of the Administration.[5]

The specific functions performed within the Office of the Secretary include budget review, review of personnel management, enforcement coordination, information management

[i] The prior incarnation of DTSC was as the Toxic Substances Control Program, a Branch of the Department of Health Services. *See* The History of the California Environmental Protection Agency: Department of Toxic Substances Control, last updated January 19, 2006, http://www.calepa.ca.gov/About/History01/dtsc.htm.

[ii] OEHHA originated under the auspices of the Department of Health Services. *See* The History of the California Environmental Protection Agency: Office of Environmental Health Hazard Assessment, last updated January 19, 2006, http://www.calepa.ca.gov/About/History01/oehha.htm.

[iii] The pesticide regulation program under the California Department of Food and Agriculture became DPR. *See* The History of the California Environmental Protection Agency: Department of Pesticide Regulation, last updated January 19, 2006, http://www.calepa.ca.gov/About/History01/dpr.htm.

coordination, strategic planning, and pollution prevention. In addition to these agency duties, the California Legislature has given the Office of the Secretary several specific programmatic responsibilities on issues including children's environmental health, enforcement, and environmental justice, among others.[6]

This report evaluates current regulatory programs under three of the CalEPA BDOs, including the Department of Toxic Substances Control (DTSC), Office of Environmental Health Hazard Assessment (OEHHA), and Air Resources Board (ARB). An analysis of programs administered by the Integrated Waste Management Board and the State Water Resources Control Board would provide further insight into existing authorities and activities on which to draw in crafting a comprehensive chemicals policy.[iv]

As a general overview, the broad missions of DTSC, OEHHA, and ARB are as follows:

- DTSC regulates the generation, treatment, storage, and disposal of hazardous waste and oversees the clean up of hazardous waste sites. DTSC also is responsible for implementing state and federal regulations dealing with the management of hazardous waste.[7]

- The smallest of the six BDOs, OEHHA is not a regulatory agency in the traditional sense. It is the only office in CalEPA that has no enforcement authority, and its regulatory powers are limited. OEHHA is commonly known as the scientific arm of CalEPA. Through its assessments, OEHHA helps establish the scientific basis for other regulatory programs, both within and outside of CalEPA, including those dealing with criteria air pollutants and air toxics, pesticides, drinking water safety, and hazardous waste. State agencies using such information include all boards and departments within CalEPA, as well as the Department of Health Services, Department of Food and Agriculture, Office of Emergency Services, Department of Fish and Game, and Department of Justice. OEHHA is also the lead agency for Proposition 65, the 1986 initiative approved by California voters to identify chemicals that cause cancer and reproductive harm.[8]

- ARB is governed by an 11-member board appointed by the governor. Six of the members are experts in fields such as medicine, chemistry, physics, meteorology, engineering, business, and law. Five others are elected officials who represent regional air pollution control agencies—one each from the Los Angeles region, the San Francisco Bay area, San Diego, the San Joaquin Valley, and another to represent more rural areas of the state. ARB sets and enforces emission standards for motor vehicles, fuels, and some consumer products; sets air quality standards; monitors outdoor air quality; identifies and sets control measures for toxic air contaminants; and provides compliance assistance for businesses. ARB also oversees the activities of 35 local and regional air pollution control districts, which regulate most non-vehicular sources of air pollution. These districts issue permits, develop local plans to attain healthy air quality, and ensure that the industries in their area adhere to air quality mandates.[9]

[iv] For example, the Integrated Waste Management Board's extended producer responsibility policies may provide insight into ways such policies could and should be incorporated into a comprehensive chemicals policy. *See* Extended Producer Responsibility (EPR) and Stewardship, last updated July 2, 2008, http://www.ciwmb.ca.gov/EPR/Activities/default.htm.

B. California's Green Chemistry Initiative

In April 2007, CalEPA Secretary Linda Adams launched the Green Chemistry Initiative with the desired outcome of "develop[ing] a coordinated, comprehensive strategy designed to foster the development of information on the hazards posed by chemicals, ways to reduce exposure to dangerous substances, approaches that encourage cleaner and less polluting industrial processes, and strategies to encourage manufactures to take greater responsibility for the products they produce."[10] According to Secretary Adams, the "Initiative will include a baseline assessment of existing programs, expertise and approaches related to the health and environmental effects of toxic chemicals and their sources, the identification of missing elements or 'gaps' in how exposure to toxic chemicals is prevented or controlled, and the analysis of multi-media impacts."[11] In her letter to CalEPA's BDOs, Secretary Adams acknowledged that "[t]o date, much of [CalEPA's] environmental protection emphasis has been to identify, reduce and control pollutants, wastes, and discharges."[12]

Secretary Adams charged DTSC with leading the effort on her behalf in collaboration with the CalEPA BDOs, indicating that CalEPA "must have a better understanding of the toxicological and environmental effects of the toxic substances in products, in processes, and in commerce."[13] Secretary Adams charged DTSC with submitting policy recommendations by July 1, 2008, to address the Green Chemistry Initiative's stated goals.[v,14]

In an attempt to include a broad array of perspectives in the creation of these policy recommendations, DTSC established and maintains a website blog through which it posts questions for interested stakeholders to respond. The questions have helped frame the ongoing Green Chemistry Initiative discussion. Some of the questions include:

1. How much should the tax be on hazardous chemicals produced, used, or distributed in California?
2. What information would trigger a ban of a chemical by the state of California?
3. What incentives should the state of California provide to promote the development of safer chemical or product alternatives?
4. What would be the appropriate response by the state of California for failure to use safer alternatives?
5. What would be the appropriate response by the state of California for failure to disclose product ingredients?
6. By what date should the state of California require reusable or biodegradable non-petroleum based packaging?
7. What lines of scientific data (in vitro toxicity and other relevant properties) should the state of California consider and use for decision-making in the absence of traditional animal toxicity data?
8. What criteria should the state of California require as part of alternatives assessments by industry in determining which products are safer/greener?
9. How should the state of California use data (generated by others) in the chemical matrix for deciding which products are safe?

[v] As of July 14, 2008, the final recommendations have not been formally submitted. On July 1 and 9, documents summarizing the findings and recommendations of six workgroups were posted on the DTSC website, but these do not appear to be the final recommendations from DTSC to Secretary Adams, nor do they address all of the stated goals of the Green Chemistry Initiative.

In addition to the website blog, DTSC has hosted multiple stakeholder meetings to get feedback from affected and interested parties as it develops policy recommendations to present to Secretary Adams. DTSC also convened a scientific advisory panel comprised of twenty-one academics, scientists, and members from industry and non-profit organizations to assist DTSC in evaluating possible options for reform.

C. Relevant California Laws

As noted above, existing CalEPA BDO authorities and activities address human exposure to some hazardous chemicals. This section describes some of the programs administered by OEHHA, DTSC, and ARB that serve to provide information on or attempt to control exposures to chemicals characterized as hazardous.

i. Proposition 65

Passed as a ballot initiative in 1986, Proposition 65, also known as the Safe Drinking Water and Toxic Enforcement Act of 1986, requires California to establish and update a list of chemicals known to the state to cause cancer or reproductive toxicity.[15] This list, which must be updated at least once a year, includes approximately 775 chemicals.[16] For purposes of implementing the provisions of Proposition 65, OEHHA identifies and determines "acceptable" levels of exposure to chemicals and contaminants on the Proposition 65 list.

Proposition 65 also imposes requirements and restrictions on the business community. First, Proposition 65 provides that a business may not expose an individual to a chemical on the Proposition 65 list without giving a "clear and reasonable warning" to the individual.[17] Once a chemical is added to the Proposition 65 list, businesses have 12 months to comply with warning requirements set out in the law.[18] Notably, Proposition 65 does not prohibit or in any way restrict the use of chemicals designated as carcinogens or reproductive toxicants, except as noted below with respect to drinking water. Exposures at any level above the maximum allowable level are permitted as long as an appropriate warning is provided.

Second, Proposition 65 prohibits California businesses from knowingly discharging listed chemicals into sources of drinking water or onto land where the chemical would pass or likely pass into a source of drinking water.[19] Once a chemical is listed, businesses have 20 months to comply with the discharge prohibition.[20]

Small businesses with less than 10 employees, governmental agencies, and public water systems are exempt from the warning requirement and discharge prohibition.[21]

Listing Chemicals

The Proposition 65 list of chemicals contains a wide range of naturally occurring and synthetic chemicals known to cause cancer, birth defects, or other reproductive harm. These chemicals include additives or ingredients in pesticides, common household products, food, drugs, dyes, and solvents. Listed chemicals may also be used in manufacturing and construction, or they may be byproducts of chemical processes, such as motor vehicle exhaust.[22]

There are four ways for a chemical to be added to the Proposition 65 list.[23] A chemical can be listed if either of two committees of scientists and health professionals finds that the chemical has been clearly shown to cause cancer, birth defects, or other reproductive harm. The two committees are the Carcinogen Identification Committee (CIC) and the Developmental and

Reproductive Toxicant (DART) Identification Committee. The second way for a chemical to be listed is if an organization designated as an "authoritative body" by the CIC or DART Identification Committee has identified it as causing cancer, birth defects, or other reproductive harm. The following organizations have been designated as authoritative bodies: the U.S. Environmental Protection Agency, U.S. Food and Drug Administration, National Institute for Occupational Safety and Health, National Toxicology Program, and International Agency for Research on Cancer. The third way for a chemical to be listed is if an agency of the state or federal government requires that it be labeled or identified as causing cancer, birth defects, or other reproductive harm. Most chemicals listed in this manner are prescription drugs. The fourth way requires the listing of chemicals meeting certain scientific criteria and identified in the California Labor Code as causing cancer, birth defects, or other reproductive harm.

"Clear and Reasonable" Warnings

One major provision of Proposition 65 requires that "clear and reasonable" warnings be provided for listed chemicals, unless exposure is low enough to pose no significant risk of cancer or is significantly below levels observed to cause birth defects or other reproductive harm.[24] In order to guide businesses in determining what exposure threshold necessitates a warning, OEHHA has developed "safe harbor" numbers. A business has "safe harbor" from Proposition 65 warning requirements if exposure to a chemical occurs at or below these levels. These "safe harbor" numbers consist of no significant risk levels for chemicals listed as causing cancer and maximum allowable dose levels for chemicals listed as causing birth defects or other reproductive harm. OEHHA has established "safe harbor" numbers for nearly 300 of the 775 listed chemicals.

For a chemical that causes cancer, the "no significant risk level" is defined as the level of exposure that would result in not more than one excess case of cancer in 100,000 individuals exposed to the chemical over a 70-year lifetime. In other words, a person exposed to the chemical at the "no significant risk level" for 70 years would not have more than a one in 100,000 chance of developing cancer as a result of that exposure. For chemicals that are listed as causing birth defects or reproductive harm, the "no observable effect level" is determined by identifying the level of exposure that has been shown to not pose any harm to humans or laboratory animals. Proposition 65 then requires this "no observable effect level" to be divided by 1,000. Businesses subject to Proposition 65 are required to provide a warning if they cause exposures to chemicals listed as causing birth defects or reproductive harm that exceed 1/1000th of the "no observable effect level."

Proposition 65 warnings are required in a variety of contexts, including for consumer products, discharges from manufacturing or distribution facilities, and exposures that may occur as a result of entering or residing in certain buildings. The law requires that a warning be "clear and reasonable," which could include labeling but also permits the posting of notices at the point of sale or entry. To emphasize the point, the law does not require that an individual consumer product be labeled. Moreover, Proposition 65 warnings do not identify the chemical or chemicals to which the warning refers, nor do they provide any information on levels of exposure that are expected to occur as a result of using the product or the potential hazards associated with those levels of exposure.

Businesses are not required to provide OEHHA with any information regarding their Proposition 65 warnings. The decision to provide a Proposition 65 warning is made by the respective business based upon its knowledge of the types of chemical exposures it is responsible for causing to individuals. A business is not required to notify OEHHA or any other regulatory agency when it decides to provide a warning.[25]

Enforcement
The California Attorney General's Office and any district attorney or city attorney (for cities whose population exceeds 750,000) have the authority to enforce Proposition 65. In addition, any individual acting in the public interest may enforce Proposition 65 by filing a lawsuit against a business alleged to be in violation of the law. Penalties for violating Proposition 65 by failing to provide warnings can be as high as $2,500 per violation per day.

ii. California's Hazardous Waste Laws

California's hazardous waste laws are a complicated web of statutes and regulations with different requirements for different types of waste. The discussion below is by no means a complete overview of these laws. Rather, it gives readers a sense of how California handles chemicals on the back end, with hazardous waste reduction measures largely being voluntary. Other California pollution prevention laws target specific industries for source reduction through trainings and incentives. Local pollution prevention programs play a role in source reduction within the state as well.

Hazardous Waste Source Reduction and Management Review Act of 1989 (SB 14)
California has adopted a statewide goal of reducing the generation of hazardous waste by 5 percent per year.[26] Senate Bill 14 (Roberti, 1989), also known as the Hazardous Waste Source Reduction and Management Review Act of 1989,[27] requires hazardous waste generators to look at their waste-generating processes and identify source reduction opportunities.[28] "Source reduction" includes, but is not limited to, all of the following:

- "Input change," which means a change in raw materials or feedstocks used in a production process or operation so as to reduce, avoid, or eliminate the generation of hazardous waste;
- "Operational improvement," which means improved site management so as to reduce, avoid, or eliminate the generation of hazardous waste;
- "Production process change," which means a change in a process, method, or technique which is used to produce a product or a desired result, including the return of materials or their components, for reuse within the existing processes or operations, so as to reduce, avoid, or eliminate the generation of hazardous waste; and
- "Product reformulation," which means changes in design, composition, or specifications of end products, including product substitution, so as to reduce, avoid, or eliminate the generation of hazardous waste.[29]

The requirements of SB 14 only apply to routinely generated waste streams from ongoing processes or operations and regularly scheduled maintenance.[30] The requirements do not apply to certain waste streams, including motor vehicle fluids, household hazardous waste, asbestos, PCBs, emergency response, lab-scale research waste, lead acid batteries, site clean up, medical waste, demolition waste, and universal waste (i.e., batteries, thermostats, electric lamps, cathode ray tubes, and television screens and monitors), among others.[31]

Generators must prepare the following three documents if they routinely generate more than 12,000 kilograms (26,400 pounds) of hazardous waste or 12 kilograms (26.4 pounds) of extremely hazardous waste:[32]

(1) Source Reduction Evaluation Review and Plan: Prepared by generators every four years, requires generators to identify all routinely generated hazardous waste streams that meet

specific weight requirements and result from ongoing processes or operations; estimate the quantity of hazardous waste generated; evaluate alternatives to, or modifications of, their processes, operations, and procedures that may be implemented to reduce the amount of hazardous waste generated; specify their plan to implement the "technically feasible" and "economically practicable" source reduction measures with a timetable; and evaluate the effects of the chosen source reduction method on emissions and discharges to air, water, or land.[33]
(2) Hazardous Waste Management Performance Report: Prepared by generators every four years, documents the hazardous waste management approaches implemented by the generator, including an estimate of the quantity of hazardous waste generated and managed, information about each source reduction, recycling, or treatment technology implemented, and a description of factors that have affected hazardous waste generation and management.[34]
(3) Summary Progress Report (SPR): Prepared by generators every four years, summarizes the results of implementing the source reduction methods identified in the generator's review and plan for each waste stream, including an estimate of the amount of anticipated reduction.[35]

These documents must be kept on the facility site where the hazardous waste is generated and made available upon request by a jurisdiction's Certified Unified Program Agency (CUPA), DTSC, or the public.[36] Only the SPR must be submitted to DTSC. The Plan and Performance Reports need not be sent to DTSC, unless expressly requested by DTSC. A hazardous waste generator may claim some information in its documents as trade secret or confidential.

Senate Bill 1916
Senate Bill 1916 (Sher, 1998) augmented existing activities conducted by DTSC to promote hazardous waste source reduction. It specified a set of activities designed to collect information and promote source reduction of hazardous waste using education, outreach, and other voluntary techniques.[37] It required DTSC to identify targeted industries and waste streams; summarize available data on hazardous waste generation and management patterns; estimate quantities by waste stream, industrial source, and handling practice; and evaluate source reduction progress and accomplishments.[38] Among other things, it required DTSC to conduct an inventory and analysis of existing low-cost voluntary programs to reduce hazardous waste generation and other toxic releases and to develop other voluntary measures to further reduce the generation of hazardous waste by large California businesses.[39]

SB 1916 also required DTSC to establish a technical assistance and outreach program to promote implementation of model source reduction measures in priority industry categories and to provide source reduction training and resources to CUPAs, small business development corporations, business environmental assistance centers, and other regional and local government environmental assistance programs that provide technical assistance to generators in identifying and applying methods of source reduction.[40]

SB 1916 established the California Source Reduction Advisory Committee to help evaluate the progress of DTSC's source reduction program and provide advice on pollution prevention program priorities.[41]

Hazardous Waste Generator Fees
Every generator that produces five tons (10,000 pounds) or more of hazardous waste in a calendar year must pay the state a generator fee for each generator site.[42] The fee increases based on the amount of hazardous waste generated with $185 as the floor and roughly $74,000 as the ceiling for generators that produce 2,000 tons (4 million pounds) or more of hazardous waste per year. Generators that pay an annual facility fee for a specific site do not have to pay a generator fee for that site.[43]

iii. California's Air Toxics Program

The Air Resources Board's (ARB) air toxics program was established in the early 1980s. The Toxic Air Contaminant Identification and Control Act (AB 1807, Tanner 1983) created California's program to reduce exposure to air toxics, mandating ARB to identify and control toxic air contaminants, except in their pesticidal use.[vi] The Act defines a "toxic air contaminant" as an air pollutant that may cause or contribute to an increase in mortality or an increase in serious illness, or that may pose a present or potential hazard to human health.[44] The Act contains precautionary language, stating that "while undisputed scientific evidence may not be available to determine the exact nature and extent of risk from toxic air contaminants, it is necessary to take action to protect public health."[45]

Under the Act, ARB prepares identification reports on candidate substances under consideration for listing as toxic air contaminants (TACs). ARB is required to use certain criteria in prioritizing the identification and control of air toxics, including the risk of harm to public health, amount or potential amount of emissions, manner of, and exposure to, usage of the substance in California, persistence in the atmosphere, and ambient concentrations in the community.[46]

The Air Toxics "Hot Spots" Information and Assessment Act (AB 2588, Connelly 1987) supplements the TAC Program by requiring a statewide air toxics inventory, notification of people exposed to a "significant health risk", and facility plans to reduce these risks.[47] ARB is required to use information gathered through the Air Toxics "Hot Spots" Program to include in the prioritization of substances under the TAC Identification and Control Act. Other relevant programs include the Children's Environmental Health Protection Act and ARB's program regulating specific categories of consumer products.

Toxic Air Contaminant Program (AB 1807)[48]

In 1983, California established a two-step process of identification and regulatory action to address the potential health effects from air toxics. During the first step, ARB and OEHHA[vii] conduct a risk assessment to determine if a substance should be formally identified as a TAC in California based on the potential for human exposure and possible health effects. After the opportunity for public input through comment periods and workshops, the report is submitted to a nine-member Scientific Review Panel (SRP), which reviews the report for its scientific accuracy. Based on the SRP's scientific findings, ARB prepares draft regulations to formally identify the substance as a TAC. Any person may petition ARB to review a previous determination by providing new evidence. As of February 2008, ARB had listed roughly 20 substances as TACs.[49]

In the second step, ARB reviews the emission sources of an identified TAC to determine if any regulatory action is necessary to reduce the emissions. The analysis includes a review of controls already in place, the available technologies and associated costs for reducing emissions, and the associated risk. As part of this step, ARB attempts to "balance public health protection and economic growth."

[vi] The Act requires the Department of Pesticide Regulation to evaluate pesticides as toxic air contaminants.

[vii] Until the early 1990s, the Department of Health Services did the work now performed by OEHHA for the TAC Program.

In 1993, the California Legislature amended the TAC Program, requiring ARB to identify the 189 federal hazardous air pollutants (HAPs) as TACs, thereby obviating the identification phase for these substances (AB 2728, Tanner).

TAC Identification Phase[50]

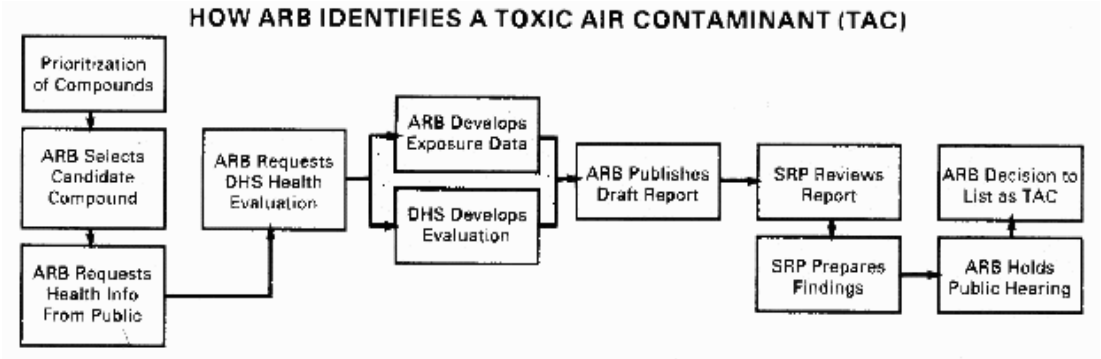
Based on criteria set forth in the law, ARB and OEHHA adopted a prioritization scheme for reviewing potentially toxic substances. The law requires ARB and OEHHA to prioritize the "evaluation and regulation of substances based on factors related to the risk of harm to public health, amount or potential amount of emissions, manner of, and exposure to, usage of the substance in California, persistence in the atmosphere, and ambient concentrations in the community."[51] In weighing the importance of these factors, ARB and OEHHA must consider research and monitoring data collected by the U.S. Environmental Protection Agency, the state board, and local air districts; emissions inventory data for substances subject to the Air Toxics "Hot Spots" Program and the risk assessments prepared for the substances; toxic chemical release data; and information on estimated actual exposures to substances based on geographic and demographic data.[52]

Once ARB and OEHHA select the substances to enter the toxics identification phase, ARB circulates to the public a request for relevant information on the health effects of the substance. OEHHA reviews all available scientific data associated with the health effects of the substance, determines whether a threshold exposure level exists below which human health effects do not occur, makes an assessment of the health risks posed by exposure to the substance, and prepares recommendations regarding effects.

Simultaneous with OEHHA's preparation of the health evaluation, ARB prepares an exposure assessment, including information on the substance's usage, emissions or potential emissions, persistence in the environment, ambient concentrations, and present or potential public exposure. OEHHA's health effects evaluation and ARB's exposure assessment become the risk assessment report, which serves as the technical foundation for determining if the substance should be listed as a toxic air contaminant in California.

ARB makes the draft report available for public comment. The Scientific Review Panel then reviews the report and makes recommendations to ARB on whether to identify a substance as a toxic air contaminant. After a public hearing, ARB determines whether to list the substance as a TAC in the California Administrative Code. The time period for this identification phase is approximately 14 months. Figure 2 graphically depicts the TAC identification phase.

Figure 2



TAC Regulatory Action Phase[53]

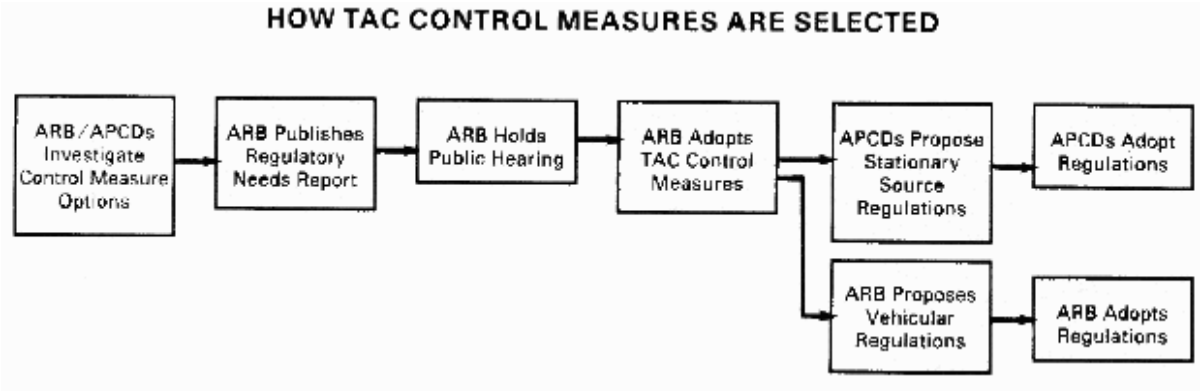
With the help of local air pollution control districts and in consultation with affected sources and the public, ARB prepares a report on the extent to which regulation is needed for an identified toxic air contaminant. Information covered in the report includes: emissions, exposure, persistence, numbers and contribution of sources, controls for such sources (including their availability, feasibility, cost, and risk reduction potential),[54] substitute substances, adverse health impacts, and magnitude of risk.

The regulatory needs report is the basis for ARB decisions to require control measures to reduce emissions of airborne toxics from stationary sources. This report also may serve as the basis for the adoption of regulations to control toxic emissions from mobile sources, such as setting emission standards for vehicular sources or standards for motor vehicle fuels.

As part of the decision-making process, the law requires ARB to consider whether a threshold for significant effects has been identified for the TAC. For substances with a designated threshold, sources are required to operate in a manner that ensures the threshold is not exceeded. When a threshold cannot be demonstrated, control measures are identified that reduce emissions to the lowest achievable level using best available control technology "unless another level is determined by a risk assessment to be adequate."[55]

Within six months of ARB's decision to adopt a control measure for stationary sources, local air pollution control districts are required to adopt regulations that are at least equally as effective. Regulations to control airborne toxic emissions from mobile sources are the responsibility of ARB. Figure 3 graphically depicts the regulatory action phase.

Figure 3



Air Toxics "Hot Spots" Program (AB 2588)[56]

In 1987, California signed into law the Air Toxics "Hot Spots" Information and Assessment Act (AB 2588, Connelly), requiring stationary sources to report their air toxics emissions, ascertain health risks, and notify nearby residents of "significant" risks. Relevant emissions include those that result from the routine operation of a facility or that are predictable, including, but not limited to, continuous and intermittent releases and process upsets or leaks. In September 1992, the Air Toxics "Hot Spots" Act was amended by Senate Bill 1731 (Calderon), requiring facilities that pose a "significant" health risk to the community to create a plan for reducing their emissions and potential harm to the community.

Substances Covered by "Hot Spots" Program

The "Hot Spots" Act requires ARB to compile and maintain a list of substances posing chronic or acute health threats when present in the air. The Act currently identifies by reference over 600 substances subject to the program. The substances included on the Air Toxics "Hot Spots" Program list are substances found on lists developed by the International Agency for Research on Cancer (IARC), the U.S. Environmental Protection Agency, the U.S. National Toxicology Program, ARB (TAC list), the California Hazard Evaluation System and Information Service, and California's Proposition 65 list of carcinogens and reproductive toxicants.[57]

Facilities Subject to "Hot Spots" Program Requirements

A facility is subject to the Act if it: (1) manufactures, formulates, uses, or releases a substance subject to the Act (or substance which reacts to form such a substance) and emits 10 tons or more per year of total organic gases, particulate matter, nitrogen oxides, or sulfur oxides; (2) is listed in any local air district's existing toxics use or toxics air emission survey, inventory, or report released or compiled by a district; or (3) manufactures, formulates, uses, or releases a substance subject to the Act (or substance which reacts to form such a substance) and emits less than 10 tons per year of criteria pollutants and is subject to emission inventory requirements.

The Act requires facilities subject to the program to prepare an air toxics emission inventory plan, which provides a comprehensive and detailed description of the methods that will be used to quantify air releases or potential air releases of listed substances from all points of release.[58] Once a local air district approves a plan, the facility operator must implement the plan and submit an emission inventory report to the district within 180 days. The report includes a facility diagram; the results of all source tests, material analysis, and other measurements performed; among other information. Facilities subject to the program also must update their emission inventories every four years. ARB maintains the toxics emissions data in the Air Toxics Emission Inventory Data System (ATEDS), which is available upon request. The emissions data also is used in the TAC Program for identifying, establishing priorities for, and controlling TACs.[59]

Risk Assessments

After reviewing emission inventory data, local air districts must rank facilities for purposes of risk assessment into high, intermediate, and low priority categories. In establishing priorities, the district must consider the potency, toxicity, quantity, and volume of hazardous materials released from the facility, the proximity of the facility to potential receptors, and any other factors the district determines may indicate that the facility may pose a significant risk. The district is required to hold a public hearing prior to the final establishment of priorities and categories.

Within 150 days of the designation of priorities, the operator of every facility that has been included within the highest priority category must prepare and submit to the districts a health risk assessment. A risk assessment, as defined under the Air Toxics "Hot Spots" Act, includes a comprehensive analysis of the dispersion of hazardous substances into the environment, the potential for human exposure, and a quantitative assessment of both individual and population wide health risks associated with those levels of exposure. In addition, the district *may* require facilities in the intermediate and low priority categories to submit a health risk assessment.

Once risk assessments are reviewed by OEHHA and approved by the districts, facility operators must notify all exposed persons of the risk assessment results if the district determines that there is a potentially significant health risk associated with emissions from the facility.

SB 1731 (Calderon), which amended the Air Toxics "Hot Spots" Program in 1992, directed OEHHA to adopt risk assessment guidelines for the program. Consequently, OEHHA established a standardized procedure for generating health-based values (called reference exposure levels) to be used for assessing heath risks within the risk assessment process under the Air Toxics "Hot Spots" Program.[60] OEHHA prioritized substances subject to the program for the development of acute and chronic reference exposure levels (RELs). Based solely on health considerations, a REL is "an airborne level that would pose no significant health risk to individuals exposed to that level for an indefinite period of time."[61] Some of the factors taken into consideration to prioritize chemicals for the development of a REL include the availability of California ambient air quality standards, the magnitude of emissions in California, and known toxic properties.[62]

Plans for Implementing Control Measures

SB 1731 also added the requirement that facilities determined by local air districts to pose a significant health risk to the community must conduct an audit of the potential harm caused by air toxics associated with the facility and develop a plan to implement measures to decrease such harm. The audit and plan must be submitted to the district within 6 months of the determination. It must describe the methods the facility will use to reduce its potential impacts below the level of significance within 5 years, although the district may shorten or lengthen the time period under certain conditions.

Public Access to Information

The emissions data collected under the Air Toxics "Hot Spots" Program must be available to the public. Accordingly, ARB developed an internet-based mapping tool that depicts some of the "Hot Spots" emissions data. Called the Community Health Air Pollution Information System (CHAPIS), the map includes about 2,000 large industrial and small commercial facilities based on information provided to ARB by the local air districts. If requested, districts must make health risk assessments available for public review. Districts also must publish annual reports that summarize the health risk assessment program, rank facilities according to the cancer risk posed, identify the facilities posing non-cancer health risks, and describe the status of the development of control measures.

Funding for the Program

The Air Toxics "Hot Spots" Act requires that ARB develop and adopt a fee regulation that recovers the state costs to implement the program. The regulation also requires each district to adopt a fee schedule which recovers the costs to the district. As of 2005, the average annual fee was $100 per facility, with the fees ranging from $35 to $3636.[63]

Children's Environmental Health Protection Act

Signed into law in 1999, the Children's Environmental Health Protection Act (SB 25, Escutia) sought to evaluate the impacts of air toxics on children, recognizing the special vulnerability of this population to the effects of toxic contaminants.

Review of State Ambient Air Quality Standards

Among other things, the Children's Environmental Health Protection Act directed ARB and OEHHA to evaluate the state's ambient air quality standards to determine whether they adequately protected children and infants.[64] ARB and OEHHA published a report in 2000, summarizing the findings of this initial review and prioritizing the standards for further review and possible revision.[65] Since this initial report, ARB and OEHHA have been reviewing the standards more extensively and ultimately adopting stronger standards, beginning with particulate matter, sulfates, ozone, and nitrogen dioxide. The second tier of pollutants yet to be reviewed includes lead, carbon monoxide, hydrogen sulfide, and sulfur dioxide.[66]

The law requires OEHHA to consider the following in making recommendations to ARB for revising the state's ambient air quality standards:

- Exposure patterns among infants and children that are likely to result in disproportionately high exposure to ambient air pollutants in comparison to the general population;
- Special susceptibility of infants and children to ambient air pollutants in comparison to the general population;
- Effects on infants and children of exposure to ambient air pollutants and other substances that have a common mechanism of toxicity, and;
- Interaction of multiple air pollutants on infants and children, including the interaction between criteria air pollutants and toxic air contaminants.[67]

TACs of Particular Concern to Infants and Children

The Children's Environmental Health Protection Act further required OEHHA, in consultation with ARB, to establish by July 1, 2001, a list of five substances classified as toxic air contaminants that may cause illness especially to infants and children.[68] In developing the list, OEHHA was required to take into account "public exposures to toxic air contaminants, whether by themselves or interacting with other toxic air contaminants or criteria pollutants"; the potency, mode of action, and other relevant biological factors of the substance being reviewed; and the list of factors in bullet form above.[69] Based on this list, the Act requires ARB to review and, if appropriate, revise or adopt new control measures for the five TACs to reduce exposure to these toxic substances.[70]

OEHHA adopted a prioritization scheme to select five TACs that posed a particular hazard to infants and children.[71] Starting with the list of approximately 200 identified TACs with data on ambient air concentrations and chronic reference exposure levels (RELs),[viii] OEHHA prioritized them based on their toxicity and extent of air emissions (utilizing emissions inventory data from the Air Toxics "Hot Spots" Program) or measured ambient concentrations in the state.[ix] OEHHA also used the following criteria to prioritize the substances:

1. Any evidence indicating that infants and children may be more susceptible than adults to the toxicological effects associated with that TAC. (For example, OEHHA determined

[viii] A chronic REL is an airborne concentration at or below which adverse noncancer health impacts would not be anticipated.

[ix] For carcinogens, this was determined by multiplying the cancer unit risk factor established by OEHHA by the ambient air concentration, which provided an estimate of the cancer risk posed by the chemical. A cancer unit risk factor describes the additional risk of cancer associated with inhaling air containing one microgram of a specified carcinogen per cubic meter. For the noncarcinogenic chemicals, OEHHA divided the ambient air concentration by the chronic REL, which provided a noncancer hazard quotient.

whether any of the chemicals included a toxicological endpoint associated with increased susceptibility in a developing organism, such as neurotoxicity, immunotoxicity, endocrine toxicity, respiratory toxicity, or developmental toxicity.)
2. The nature and severity of the effect(s), especially irreversible effects.
3. Any evidence indicating that, based on current risk assessment methodology, the existing health criteria may not be adequately protective of infants and children.
4. Any potential difference in susceptibility of infants and children relative to adults to carcinogenesis based on known information or plausible mechanisms.
5. The extent of exposure and/or the magnitude of risk estimated to occur at concentrations typical of California urban ambient air, and any indication that infants and children may be more heavily exposed to materials contaminated by airborne particles such as in household dust.

Of the more than 200 TACs, OEHHA chose thirty-six chemicals for focused literature reviews. Based on the strength of the toxicity data for the TACs and extent of exposure, OEHHA narrowed the list to seventeen TACS. Of the seventeen, OEHHA chose five TACs for initial listing under SB 25 as directed by the law.

Continued Evaluation of TACs

Beginning July 1, 2004, OEHHA is required to annually evaluate at least fifteen TACs identified by ARB until all toxic air contaminants are evaluated under the Children's Environmental Health Protection Act. Again, OEHHA must take into account the potency, mode of action, and other relevant biological factors of the substance being reviewed as well as the list of factors in bullet form above.[72]

The Act requires ARB to adopt, if appropriate, new control measures for the identified TACs to reduce exposure to these contaminants.[73]

Children's Environmental Health Center

The Children's Environmental Health Protection Act also created the Children's Environmental Health Center within CalEPA to advise the Secretary for Environmental Protection and the Governor on matters within the jurisdiction of the agency relating to environmental health and environmental protection as it relates to children.[74]

Consumer Products Regulation

In 1988, the Legislature enacted the California Clean Air Act, which added a number of new provisions to the Health and Safety Code, including new authority for ARB to regulate volatile organic compound (VOC) emissions from consumer products.[75] Broadly defined, "consumer product" means a "chemically formulated product used by household and institutional consumers, including, but not limited to, detergents; cleaning compounds; polishes; floor finishes; cosmetics; personal care products; home, lawn, and garden products; disinfectants; sanitizers; aerosol paints; and automotive specialty products; but does not include other paint products, furniture coatings, or architectural coatings."[76] ARB's regulatory authority over consumer products does not cover products made in California for sale or use outside of the state.[77]

State law requires ARB to adopt regulations to achieve the maximum feasible reduction in VOCs emitted by consumer products, if the state board determines that adequate data exist to establish that: (1) the regulations are necessary to attain state and federal ambient air quality

standards, and (2) the regulations are commercially and technologically feasible and necessary.[78] ARB does not have the authority to consider whether a product's VOCs create indoor air pollution or otherwise may harm the health of the end user specifically. Notably, ARB may not adopt a regulation that requires the elimination of a product form.[79]

To regulate VOCs in consumer products, ARB identifies categories of products that emit VOCs and sets limits on the amount of particular VOCs that each type of product may emit.[80] Product categories currently covered by ARB's regulations include air fresheners, windshield washer fluids, household cleaners, antiperspirants and deodorants, and charcoal lighter fluid, among many others.

In determining the VOC limits for targeted product categories, ARB looks at a variety of data. It relies on data generated from mandatory reporting requirements for all manufacturers of goods sold in California in each specified product category on the type and levels of VOCs (or other targeted chemicals) in the product. If the data within a particular product category reveals that some manufacturers make the product with lower VOC levels than their competitors, ARB will propose to set the VOC limit at this lower level. In addition, ARB reviews scientific reports, including information on new technologies, and looks to standards set in other countries to support its proposals for lowering the VOC levels in a given product category.

In addition to the specific authority granted to ARB to regulate VOCs in consumer products, ARB may regulate consumer products that emit two other categories of chemicals for which it has general authority to regulate: toxics that affect outdoor air quality and greenhouse gases that contribute to global warming. For the former, ARB may regulate a toxic chemical in a consumer product if it shows that the product emits a substance that negatively impacts outdoor air quality and does so to a degree that adversely and directly affects the health of nearby residents.[81] Although it is difficult to make such a showing, ARB has exercised this authority to limit toxic substances in consumer products. Specifically, ARB has prohibited the use of three chlorinated toxic air contaminants—perchloroethylene, methylene chloride, and trichloroethylene—from 63 consumer product categories.[82] ARB also has prohibited the use of para-dichlorobenzene in solid air fresheners and toilet care products. These prohibitions were accomplished using the authority provided under the California Environmental Quality Act (CEQA) or through adoption of airborne toxic control measures (ATCM).[83]

Pursuant to the California Global Warming Solutions Act of 2006 (AB 32, Nuñez/Pavley), ARB has the authority to regulate a variety of sources, including consumer products that emit greenhouse gases. Accordingly, ARB used its 2006-07 product survey to gather data on the global warming potential of the chemicals used in each of the existing VOC product categories. Because ARB is in the early stage of implementing AB 32, it is unclear how ARB will weigh the threat of global warming against manufacturers' economic concerns as to individual product categories. Unlike the law governing ARB's authority over VOCs in consumer products, AB 32 does not expressly bar ARB from promulgating regulations that would eliminate a product category. To date, ARB has proposed only one regulation pursuant to this new authority in the category of "pressurized gas dusters."

IV. CALIFORNIA'S CURRENT LAWS PROVIDE LIMITED GUIDANCE

California's existing laws provide limited guidance on the types of policies or programs that would best advance our core principles for chemicals policy reform. For the most part, the existing programs establish mechanisms for eliminating or reducing bad actor chemicals, or chemicals classified by an authoritative body as toxic for one reason or another. Setting aside for a moment the problems associated with the reliance on risk assessment, such "bad actor chemical" programs serve an important function of reducing or eliminating people's exposure to chemicals known to cause harm. They point to a glaring regulatory gap, however, with the absence of a comprehensive program that provides for the review of complete hazard data and enables the state to make broad determinations about a chemical's use.

Of the existing programs reviewed, none make regulatory decisions based solely on the intrinsic hazards or properties of a chemical. Risk assessment underlies determinations of safety and decisions to require pollution controls in all programs discussed. There are multiple problems with relying on risk assessment to make such determinations. First, because there is incomplete and inadequate information on many hazard traits about which we are concerned, determinations as to the safety of a chemical will be made without all of the necessary information. This is due in part because for some hazard traits, current testing methods are insufficient, outdated, and may not address all of the aspects of a hazard trait. Thus, reliance on the existing methods renders the data inadequate for purposes of determining the actual impact of a chemical through a risk assessment.

Second, traditional risk assessment does not factor in new concepts in science such as low-dose effects, timing of exposure, cumulative impacts, and synergistic effects. A risk assessment for a chemical is conducted in isolation without accounting for the synergistic effects with other chemicals or the cumulative impacts of the same chemical through multiple routes of exposure. The Children's Environmental Health Protection Act may provide some guidance on how to incorporate an analysis of cumulative and synergistic impacts of chemicals into evaluations of their safety, since OEHHA needs to consider the interaction of multiple air pollutants on infants and children under this law. OEHHA's considerations of the sensitivity of infants and children may also provide guidance on how to account for special sensitivities to chemicals generally. Another forum in which to look for guidance on incorporating cumulative impacts into an evaluation of a chemical's safety is the CalEPA Cumulative Impacts and Precautionary Approaches Work Group, which met for the first time in June 2008.[84]

Finally, risk assessments can often result in poorer outcomes for the public, in large part due to industry's significant involvement in the process. Conducted as part of protracted administrative processes, risk assessments receive extensive scrutiny, comment, and lobbying from those with financial interests in the outcome, but little scrutiny, comment, and lobbying from the public interest community, largely due to a lack of resources. Thus, the weight of input on risk assessments is far greater from industry and tends to skew the results. Moreover, risk assessments require a variety of assumptions to be made, and industry interests seek to make the assumptions as favorable to their outcomes as possible. And they often succeed in doing so.

None of the existing programs reviewed requires chemical manufacturers to demonstrate the safety of their chemical or to provide data sufficient for government to make determinations about a chemical's safety with respect to all of the endpoints with which many environmental health and justice advocates have significant concerns. Generally, existing programs do not

require chemical manufacturers or users of chemicals to provide any hazard data on chemicals. Through the Toxic Air Contaminants Program, for example, ARB requests relevant hazard data from the public on a chemical being reviewed for potential TAC listing.

Moreover, economic considerations are often factored into regulatory decisions on chemicals. For example, while ARB's consumer products program may reduce the emissions of particular VOCs in specified product categories, the regulations cannot result in the elimination of a product form. Thus, even if the hazard traits of a chemical might warrant the complete elimination of a particular chemical, economic and market considerations will dictate otherwise.

Proposition 65 resulted in the establishment of a list that includes chemicals determined by the state to be carcinogens or reproductive or developmental toxicants. Although risk assessment is the tool utilized to list chemicals, there is value in having such a list. First, many claim that the list of chemicals has served as an incentive for some manufacturers to reformulate their products. Second, for purposes of crafting intermediate measures in advance of the state establishing a comprehensive regulatory program to assess and act on chemicals, the Proposition 65 list could be a starting place for targeting chemicals for reduction or elimination in the short term. The Toxic Air Contaminants list may also be a useful starting place for immediate and broad determinations about restrictions on particular chemicals.

Reporting requirements found in California's hazardous waste laws may provide some useful information on the types of chemicals commonly used in California. There are far too many limitations in the data, however, for the information to help guide broad decisions about actions to be taken on chemical substances, even through a "bad actor chemical" program. These laws also do not provide for producer responsibility of products that may contain hazardous chemicals.

The reliance on fees in California's hazardous waste laws, however, could serve as a model for a viable funding mechanism. Under the state's hazardous waste laws, generators of hazardous materials must pay a fee to use such substances. The fee is not commensurate with the potential harm caused by the substances, but the idea of assessing fees for the use of hazardous chemicals is not new to the state. Such a concept could be extended and the fee substantially increased to reflect the actual potential cost. Fees from producers and users of hazardous chemicals could be an important funding source for regulatory activities aimed at protecting the public and the environment from these substances.

Many programs require coordination between CalEPA BDOs (typically, between OEHHA and another board or department). A comprehensive chemicals policy would certainly require extensive coordination among multiple BDOs. The coordination between ARB and OEHHA on multiple regulatory programs, including the Toxic Air Contaminants Program, may provide some guidance on how best to coordinate the activities of two or more CalEPA BDOs to implement comprehensive chemicals policy reform.

Across the board under the existing laws discussed, the public does not have adequate access to information, and specifically, has quite limited access via the internet. Some information collected is essentially useless to the public because of the requirements surrounding its collection and storage. For example, a couple of the SB 14 documents are only required to be kept on site at the reporting facility where the hazardous waste is generated. Although the public can request the information contained in the documents housed at the site, the lengthy process for obtaining the information effectively makes this information inaccessible.

Proposition 65's citizen suit provision proves to be a useful model for public participation and for leveraging additional resources to ensure safer consumer products. Enabling the public to enforce the warning requirements of the law through civil litigation has resulted in countless judgments and settlements requiring companies to reformulate their products containing hazardous chemicals and to pay fines to support consumer awareness efforts and health-improvement activities. Particularly in a budget crisis climate, such a mechanism provides another avenue for bringing resources to bear on toxics in consumer products. In addition, the citizen suit provision makes enforcement of Proposition 65 perhaps less susceptible to industry lobbying as compared to standard regulatory programs without such a public enforcement mechanism.

While there are lessons to be learned from California's existing laws governing chemicals, they serve more as a backdrop for the type of reform needed in the state—the creation of a robust regulatory program that provides for the collection and evaluation of comprehensive health and environmental impacts data, prohibits or restricts the use of chemicals known to cause harm or for which data do not exist to make such a determination, incorporates substitution policies that drive businesses to use safer chemicals or practices, and gives the public meaningful access to information so they may protect themselves from potential hazards.

V. REVIEWING CHEMICALS POLICY FRAMEWORKS

This section briefly summarizes the key components of existing and proposed chemicals policy frameworks within and outside the United States. Each of these frameworks approaches critical issues, such as the elimination of hazardous chemicals, data requirements for entering and staying on the market, burden of proof for demonstrating chemical safety, incorporation of chemical substitution, and access to testing data, differently. Understanding the specific elements of these existing frameworks can help inform our work as advocates of chemicals policy reform in California.

A. Toxic Substances Control Act (TSCA)

In 1976, Congress passed the primary law regulating toxic chemicals in the United States, the Toxic Substances Control Act (TSCA).[x] With the passage of TSCA, the United States Environmental Protection Agency (U.S. EPA) was given broad authority to regulate toxic substances. To the extent the act calls for the evaluation of a chemical, TSCA relies upon risk assessment as the primary tool for determining whether a chemical should be restricted due to any unreasonable risk to human health or the environment. For a number of reasons, TSCA fails to eliminate known hazards from the market.

While TSCA has had some successes in ensuring review of new chemicals coming to the market since 1980, its impact in terms of gaining information on the toxicity of chemicals and restricting existing chemicals on the market has been quite limited.

Existing Chemicals

TSCA divided all chemicals on the market into two categories: existing chemicals and new chemicals. TSCA grandfathered all existing chemicals on the market as of 1979 into use without health-effects testing or analysis—roughly 62,000 chemicals.[85] These chemicals make up approximately 99% by volume of the chemicals on the market today.[86] Most of the so-called existing chemicals emerged in the 1940s and 1950s when few laws governed chemical safety.

Under Section 6 of TSCA, existing chemicals are considered safe unless U.S. EPA can establish that: 1) they will in fact present an unreasonable risk to human health or the environment, 2) the agency is choosing the least burdensome regulation to reduce risks to a reasonable level, and 3) the benefits of regulation outweigh the costs to industry.[87] U.S. EPA must establish this on a chemical-by-chemical basis. Such a high burden has essentially paralyzed U.S. EPA from regulating or restricting chemicals predating 1980.

Since TSCA's inception, U.S. EPA has never successfully used its authority under Section 6 of the act to ban a chemical and has only formally regulated five existing chemicals or classes of chemicals, including chlorofluorocarbons, dioxin, asbestos,[xi] hexavalent chronmium, and polychlorinated biphenyls (PCBs), the last of which Congress ordered regulated through TSCA.[88] In addition, under Section 5(a)(2) of TSCA, for 160 existing chemicals, U.S. EPA

[x] Under TSCA, a chemical is defined as "any organic or inorganic substance of a particular molecular identity, including (i) any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature and (ii) any element or uncombined radical." 15 U.S.C. 2602. As a reminder, the term excludes cosmetics, food, food additives, pesticides, pharmaceuticals, tobacco, and nuclear materials.

[xi] The asbestos ban was overturned by the Fifth Circuit Court of Appeals. *See Corrosion Proof Fittings v. U.S. EPA*, 947 F.2d 1201 (5th Cir. 1991).

issued significant new use rules that require chemical companies to submit notices to U.S. EPA prior to commencing the manufacture, import, or processing of the chemical for a significant new use.[89]

When there are insufficient data to determine whether an unreasonable risk to human health or the environment exists, U.S. EPA must have sufficient evidence of potential risk associated with exposure to a chemical in order to require a chemical manufacturer to generate additional data pursuant to Section 4 of TSCA. This Catch-22 has meant that very little data has been generated. Furthermore, U.S. EPA estimates that it takes between two and ten years to finalize a rule ordering additional testing and requires the expenditure of substantial resources. In 1994, the cost estimate for issuing a rule under Section 4 was roughly $235,000.[90] Because of the significant hurdles to obtaining data through Section 4, U.S. EPA has stopped using it as a mechanism for generating data on chemicals, instead relying on negotiated consent orders with individual companies for tests on individual chemicals.[91] Companies are not required to enter into these consent processes, nor are the agreements strictly enforceable.[92]

New Chemicals

Pursuant to Section 5 of TSCA, companies that wish to introduce a new chemical to the U.S. market or introduce a "significant new use" of an existing chemical must notify U.S. EPA through a premanufacture notification (PMN) at least ninety days before introduction. The PMN contains information on the chemical identity, physical characteristics, use, and available toxicity data. U.S. EPA has ninety days to review the chemical information in the PMN and identify the chemical's potential risks. If U.S. EPA fails to act or determine within the ninety days that further review of the chemical is warranted, the company may manufacture the chemical.

For the PMN, TSCA only requires that manufacturers submit data that is "in their possession," thereby creating a disincentive for manufacturers to conduct any health-effects testing.[93] In fact, U.S. EPA estimates that most PMNs do not contain test data of any type, and only about fifteen percent include health and safety data, such as acute toxicity or skin and eye irritation data.[94] Similar to existing chemicals, the Catch-22 stymies U.S. EPA from obtaining additional data. The agency can require the testing of chemicals under Section 4 but first must show there are insufficient data to make an unreasonable risk determination and that a chemical may present an unreasonable risk. Typically, the agency must negotiate with notifying manufacturers on a case-by-case basis to provide additional information.[95] Thus, the absence of minimum data requirements for PMNs hinders U.S. EPA's ability to conduct a thorough review, especially in the ninety-day timeframe.[96]

Public Access to Information

TSCA requires U.S. EPA to protect trade secrets and confidential commercial or financial information against unauthorized disclosures.[97] The agency is given broad discretion to disclose other information it believes necessary to protect the environment or human health.

Under TSCA, companies liberally designate information they provide to U.S. EPA as confidential business information (CBI)—designations that go unchallenged by the agency. U.S. EPA is not required to review and either accept or deny CBI requests, and up front justifications are not required.[98] While it has developed criteria for what constitutes legitimate CBI claims, U.S. EPA must challenge them on a case-by-case basis, which is highly resource-intensive. CBI claims have no expiration date.[99] While health and safety information cannot be claimed as CBI, the identity of the chemical and the submitter generally can be. Thus, a chemical may be listed on the TSCA Inventory under a generic name (e.g., preservative).

TSCA prohibits the disclosure of information claimed as CBI to anyone outside the federal government (other than contractors), including state, local, and foreign governments. TSCA does not generally mandate or encourage public disclosure of information not deemed confidential.[100]

TSCA Case Study: Asbestos

U.S. EPA's attempt to regulate asbestos in 1989 demonstrates the near impossibility of restricting an existing chemical in commerce through the federal regulatory process. Following ten years of research, public meetings, and regulatory impact analyses, U.S. EPA issued a final rule under Section 6 of TSCA to prohibit the future manufacture, importation, processing, and distribution of asbestos in almost all products.[101] The asbestos industry challenged U.S. EPA's ban in federal court, taking its claim to the Fifth Circuit Court of Appeals. In a landmark case (*Corrosion Proof Fittings v. U.S. EPA*, 947 F.2d 1201 (5th Cir. 1991)), the Fifth Circuit all but eliminated U.S. EPA's ability to use TSCA Section 6 to restrict problem chemicals. Despite its acknowledgment that "asbestos is a potential carcinogen at all levels of exposure," the court held that U.S. EPA presented insufficient evidence to justify its asbestos ban. In so holding, the court found that: (1) the agency had not used the least burdensome regulation to achieve its goal of minimizing risk, (2) had not demonstrated a reasonable basis for the regulatory action, and (3) had not adequately balanced the benefits of the restriction against the costs to industry. The court criticized U.S. EPA's ban on asbestos in products for which no substitutes were currently available, indicating that U.S. EPA faced a high burden of proving the regulation was the least burdensome alternative as a result.[102] The Fifth Circuit's ruling revealed the significant hurdle U.S. EPA faces in regulating an existing chemical under TSCA, considering the extensive scientific evidence on the adverse health effects of asbestos and the fact that the agency spent ten years amassing this evidence in support of its restriction of the chemical.[103] Since the Fifth Circuit decision, U.S. EPA has not exercised its Section 6 authority to restrict chemical production or use.

B. Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH)

On June 1, 2007, the new European Union program for managing chemicals[xii]—called REACH (Registration, Evaluation, Authorization, and Restriction of Chemicals)—entered into force.[104] REACH sets out a new approach for controlling the manufacture, import, and use of chemicals in the EU. Among other things, REACH requires chemical manufacturers to provide basic health and safety information for all chemicals produced or marketed in quantities over 1 ton (2,000 pounds) a year per importer or producer, before placing them on the market (creating a concept known as the "no data, no market" principle). It also sets up a system to control "substances of very high concern" (such as persistent, bioaccumulative, or toxic chemicals) by requiring such substances to be authorized for use. REACH will require some of these substances to be substituted with safer alternatives when the alternatives become available. Notably, REACH eliminates the distinction between existing and new chemicals, imposing the same requirements detailed below for both types of chemicals. In addition, retailers and consumers will have the right to obtain information on whether chemicals on the "candidate list" (see below for discussion) are present in products they buy. REACH created the European Chemicals Agency to manage the various pieces of the regulatory program.

[xii] REACH governs "substances," which are defined to include chemical elements and their compounds in the natural state or obtained by any manufacturing process. This report uses the word "chemical" rather than "substance" for consistency in our discussion of the different chemicals policies.

Registration[105]
REACH creates a general obligation for manufacturers and importers of chemicals to submit a registration to the European Chemicals Agency for each chemical manufactured or imported in quantities of one ton (2,000 pounds) or greater per year as a condition for entering or remaining on the market. There are tiered data requirements with more data required for chemicals manufactured or imported in higher quantities, with staggered submission deadlines ranging from three to eleven years. The four tonnage bands are 1 ton or more, 10 tons or more, 100 tons or more, and 1000 tons or more per year. The failure to register a chemical results in a prohibition on the manufacture or import of the chemical. The registration process requires manufacturers and importers to submit a technical dossier with information on the properties, uses, and classification of the chemical in addition to guidance on its safe use. Downstream users of chemicals must provide the use information to the registering manufacturers or importers.

For chemicals manufactured or imported in quantities of ten tons or greater, manufacturers and importers also must submit a chemical safety report, documenting the hazards and classification of the chemical, and assessment as to whether the chemical is a PBT or vPvB (very persistent, very bioaccumulative). The chemical safety report also includes exposure scenarios for specific uses of PBTs, vPvBs, or chemicals classified as dangerous, describing how the chemicals are manufactured or used during their lifecycle and how exposures to the chemical are or should be controlled. General rules are also set out for the use of existing information; new tests are only required when it is not possible to provide the information in any other permitted way.

Information on roughly 30,000 chemicals is expected to be provided electronically through the registration process. Given the number of registrations expected, only a simple electronic completeness check will be performed by the European Chemicals Agency in the registration stage. If the registration is not rejected within a set deadline, then the registrant may begin or continue to manufacture or import the chemical.

REACH separately deals with chemicals used in “articles” (e.g., manufactured goods such as cars, textiles, or electronic chips). REACH requires all chemicals intended to be released from articles during normal and reasonably foreseeable conditions of use (e.g., scented candles) to be registered according to the normal registration rules if those substances are present in the articles above one ton per year. In addition, all chemicals of very high concern (i.e., on a list of candidate chemicals for authorization that will be produced by the Agency) present in articles above a concentration limit of 0.1% by weight and above one ton per year must be disclosed to the Agency, unless exposure to humans or the environment will not occur through normal use and disposal. In such cases, the registrant must provide safety instructions. A general proviso allows the European Chemicals Agency to require the registration of a chemical in an article if the Agency believes the chemical’s release poses a risk to human health or the environment.

Registration fees for chemicals will cover part of the cost of the registration process.

Evaluation
REACH provides for two types of evaluation—dossier evaluation and substance evaluation. As part of the dossier evaluation, the European Chemicals Agency will do a quality check of the registration dossiers to determine if the registrants comply with the registration requirements and to check the testing proposals to prevent duplicative or unnecessary animal testing. REACH requires that only five percent of the dossiers be checked for compliance with the requirements, but requires checks for all testing proposals before any tests are performed.

Under the substance evaluation, the Agency, in coordination with the EU member states, may clarify suspicions of risk to human health or the environment by requesting further information from the registrant. In order to require additional data, one EU member state must sponsor the request and all EU member states must approve the request on a chemical by chemical basis. If not all member states agree, the European Commission can make the decision to require new tests.

As part of the substance evaluation, the European Chemicals Agency, in cooperation with the EU member states, will develop guidance on the prioritization of chemicals for further evaluation on the basis of risk. The individual member states will conduct the evaluations of priority chemicals. Evaluation may lead to the conclusion that action needs to be taken under the restriction or authorization process.

Authorization[106]

The authorization process essentially provides for a presumptive ban of certain chemicals based on their hazard traits, with exemptions to the ban permitted based on an assessment of risk.

Under the authorization process, the European Chemicals Agency will publish a list of priority chemicals—known as the candidate list—that need authorization either for continued use or before they can be used (for new chemicals). The candidate list will include:

- Some carcinogens, mutagens, and reproductive toxins (CMRs),
- Persistent, bioaccumulative, and toxic chemicals (PBTs),
- Very persistent, very bioaccumulative chemicals (vPvBs), and
- Chemicals identified from scientific evidence as causing probable serious effects to humans or the environment equivalent to those above on a case-by-case basis, such as endocrine disrupters. For this last category of chemicals, the European Commission will develop guidance to clarify the criteria for case-by case determinations.

The Agency will determine which chemicals from these categories to place on the candidate list after it has reviewed the information that chemical companies submit to the Agency at the time the chemicals are registered under REACH and after considering the input provided by individual EU member states and the European Commission. From this candidate list, the European Commission will determine which chemicals will need authorization for their continued use.

Those businesses using or making available the specified chemical that still want to do so will need to apply for an authorization for each specific use of the chemical within a set period of time. Otherwise, the chemical will be banned for all uses. The European Commission will grant the authorization for specific uses if the applicant can show that the risk from the use of the chemical is adequately controlled or if the socio-economic benefits outweigh the risks and no suitable alternative chemical or process exists. The authorization process shifts the burden to industry to prove the risk is adequately controlled, unless industry can show that the socio-economic benefits outweigh the risks and no suitable alternative exists. CMRs, PBTs, and vPvBs for which a safe level cannot be defined cannot be authorized based on an adequate control of risk.

The European Union estimates that roughly 1,500 chemicals will fall into the authorization process, but others estimate that the number is much higher.

Restriction[107]

Any chemical on its own, in a mixture, or in an article may be subject to a restriction if it is demonstrated by government that there is an unacceptable risk to human health or the environment that cannot be adequately controlled. The restriction can include a complete ban of the chemical or a restriction for specific uses. Either the EU member states or the European Chemicals Agency can propose a restriction, with the European Commission making the ultimate determination. There are no deadlines for restriction decisions to be made by a date certain. All uses of a chemical that are not restricted are allowed under REACH unless the chemical is included in the authorization system. Existing chemical restrictions (such as the ban on asbestos, restrictions on the uses of certain azo-dyes, and ban on phthalates in children's products) are carried over in a consolidated version into the REACH regulation.

Public Access to Information[108]

Under REACH, information that is considered confidential cannot be shared with the public or users of chemicals. REACH treats some information as confidential even if a company does not claim it as confidential, including the following: (1) details of the full composition of the chemical's preparation; (2) the precise use, function, or application of the chemical or its preparation; (3) the precise tonnage or volume of the chemical manufactured or placed on the market; and (4) relationships between manufacturers/importers and downstream users.

Information relating to health, safety, and environmental properties, risks, and risk management measures is required to be passed up and down the supply chain. Such information includes the (1) trade name of the substance; (2) physiochemical information, pathways, and environmental fate; (3) results of toxicological and ecotoxicological studies; (4) classification and labeling requirements; (5) degree of purity of substance; (6) identity of impurities and/or additives known to be hazardous; (7) handling instructions; and (8) safety data sheet information (except for the name of the company). Importantly, this does not mean the public will have access to this information.

Some non-confidential information will be made available on the European Chemical Agency's website and some will be made available by request. For the latter category of information, the Agency must inform a chemical manufacturer of any request for documents relevant to a certain chemical. The manufacturer will have thirty days to identify the information it wishes to remain confidential. Reasons may include commercial sensitivity or commercial harm to an individual or corporation.

REACH provides broad authority to share CBI with other domestic and foreign governments.[109]

C. Canadian Environmental Protection Act (CEPA)

Originally enacted in 1988 and revised in 1999, the Canadian Environmental Protection Act (CEPA) covers a range of activities that can affect human health and the environment. CEPA 1988 focuses on pollution management, whereas the 1999 revision of CEPA focuses on pollution prevention. CEPA 1988 mandated the creation of the Domestic Substances List (DSL), which includes the roughly 23,000 chemicals in commerce in Canada. Among other things, CEPA 1999 required the Ministers of Environment Canada and Health Canada to categorize the 23,000 chemicals on the DSL based on whether they may present to Canadians the greatest potential for exposure, or whether they are persistent or bioaccumulative, and inherently toxic to humans or non-human organisms.[110]

Under CEPA 1999, a chemical is identified as "toxic" if it: (1) has or may have an immediate or long-term harmful effect on the environment or its biological diversity, (2) constitutes or may constitute a danger to the environment on which life depends, or (3) constitutes or may constitute a danger in Canada to human life or health. The definition of "toxic" makes clear that it encompasses consideration of both hazard and exposure, similar to TSCA.[111]

Unlike TSCA, however, the determination of whether a chemical is toxic under CEPA and, therefore, requires regulatory action is separate from the determination of how the potential harm should be controlled.[112] The former decision does not require consideration of economic and social factors, the benefits of the chemical, or the availability of alternatives, but these factors influence the latter decision about the type of control measures to impose.[113]

Existing Chemicals

The categorization of DSL chemicals pursuant to CEPA 1999 represented a priority setting exercise to determine which existing chemicals should be subject to screening assessments and possible control measures.[114] The categorization process was completed in September 2006. Importantly, the lack of a routine reporting requirement under CEPA meant that for the majority of DSL chemicals, the production, import, and use information relied upon was extremely dated. In addition, the information used to categorize the chemicals was based on existing, available information about their known hazardous characteristics.[115]

Of the 23,000 chemicals, 4,300 were identified as priorities for which screening-level risk assessments should be conducted to determine whether they are toxic or capable of being toxic. The 4,300 chemicals were further prioritized based on the degree of hazard and risk, commercial activity in Canada, ongoing risk assessment and management activities, and opportunities to engage internationally to decrease the burden on Canada. Of the 4,300 chemicals, roughly 500 have been designated as high priorities, 2,600 as medium priorities, and 1,200 as low priorities. Based on existing data, the 500 chemicals were deemed high priorities because they:

- Met each of the ecological categorization criteria (i.e., persistence, bioaccumulation, and inherent toxicity to aquatic organisms) and were believed to be in commerce in Canada; and/or
- Met the criteria for greatest or intermediate potential for exposure and were identified as posing a high hazard to human health (i.e., classified by another agency on the basis of carcinogenicity, mutagenicity, developmental toxicity, or reproductive toxicity).

For the 500 high-priority chemicals, about fifty are subject to risk management actions currently underway. For about 150 high-priority chemicals, companies seeking to manufacture or import these chemicals will be required to submit significant new activity notices and the Canadian government will have to review and assess the chemicals. For roughly 200 high-priority chemicals, Canada created a "Challenge to Industry" Program to encourage industry and other interested stakeholders to provide Environment Canada and Health Canada improved toxicity data; environmental release, exposure, and use information; and information about how industry manages these chemicals. For the remaining high-priority chemicals, a variety of actions are contemplated, including sector agreements and assessments of new uses.

The 2,600 medium priority chemicals are expected to be addressed by 2020 through performance agreements with industry.

In addition to mandatory screening-level risk assessments for the 4,300 chemicals, CEPA requires assessments of chemicals on the Priority Substances List (PSL)—established by CEPA—and chemicals for which provincial or international prohibitions or restrictions exist.[116] The PSL is a list of chemicals identified by the Ministers of Environment Canada and Health Canada to which priority should be given to assess their actual or potential toxicity within five years of the publication of the list. The screening assessments for all of these chemicals must lead to a proposal by the Ministers to: (1) take no action, (2) conduct a more in-depth assessment of the chemical, or (3) add it to the List of Toxic Substances and, if additional findings are made, seek to eliminate the chemical's use.[117]

The government can only impose regulations or requirements for pollution prevention plans or environmental emergency plans if the chemical is on or recommended to be added to the List of Toxic Substances. Once listed, the government has two years to develop and propose a management strategy and eighteen additional months to finalize the strategy.[118]

The policy goal for chemicals on the List of Toxic Substances that are toxic, persistent, and bioaccumulative, and whose presence in the environment results primarily from human activity is "virtual elimination" from the environment. The emphasis is on the prevention of releases, rather than their control or remediation, with chemical producers and users bearing the burden of proving the chemical can be managed throughout its lifecycle without measurable release. The policy goal for chemicals on the List of Toxic Substances that do not meet all of the above criteria is life-cycle management to prevent or minimize environmental releases. Virtual elimination is pursued only for specific products or uses where the chemical poses unacceptable risks to the environment or human health.[119]

Regulatory prohibitions and restrictions of existing chemicals have been used to a very limited extent under CEPA. As of April 2007, nine substances, including DDT and mirex, have been prohibited altogether, and another five are subject to use restrictions or concentration limits in mixtures or products. Sector-specific regulations that restrict the use of certain toxic substances have also been used, covering, for example, chlorinated solvents in degreasing and dry cleaning. Requirements for companies to develop and implement pollution prevention plans have been imposed for a handful of chemicals, groups of chemicals, or specific uses (e.g., wood preservatives). These plans, however, need only be submitted upon request. Finally, non-regulatory approaches include guidelines and codes of practice, which have been developed in some cases for specific chemicals or groups of chemicals used in specific applications or sectors, although such guidelines and codes are not enforceable.[120]

For existing chemicals, on a case-by-case basis, government can require the reporting of existing hazard, exposure, and use data. The authority to do so is similar to that under TSCA, although the burden on government is somewhat lower.[121] Like TSCA, government must have sufficient evidence of potential risk or toxicity of, or extensive potential exposure to, a chemical in order to require industry to generate new hazard data.[122] Thus, Canada is plagued with the same Catch-22 as the U.S., requiring a certain level of evidence of the potential for harm before being able to require the generation of data to assess potential harm.

New Chemicals

New chemicals are subject to data submission (through New Substance Notifications) and review prior to introduction into commerce in Canada.[123] There are tiered information requirements depending on volume and exposure criteria. The data requirements include limited hazard information. Within seventy-five days, Environment Canada and Health Canada must conduct a review of the submission to determine whether the chemical is toxic or

"suspected" of or "capable" of becoming toxic. The determination involves an assessment of the hazards and potential for exposure to humans and the environment.[124] Either hazard or potential for exposure or both can be a sufficient basis for a "suspected" finding.

If the government finds the chemical is suspected of becoming or capable of being toxic, it may: (1) permit the manufacture or import of the chemical subject to certain conditions, (2) prohibit the manufacture or import for up to two years, or (3) prohibit the manufacture or import pending submission by the chemical manufacturer or importer and assessment by the government of additional information.[125] In such situations, the assessment period may be extended.

Regulatory actions on new chemicals are taken almost entirely on a case-by-case basis and relatively infrequently.[126]

Public Access to Information

Companies must provide upfront justification of confidential business information claims, which the government reviews and must either accept or deny.[127] CBI claims do not expire.[128] CBI can be disclosed if the Minister of the Environment determines that: (1) it is in the interest of public health and safety or protection of the environment, or (2) there exists a public interest in the disclosure that either outweighs the potential financial burden or loss of competitiveness or causes damage to an individual's privacy, reputation, or human dignity. CEPA provides no specific exemption from CBI protection for health and safety information.[129]

CEPA allows for the sharing of information with domestic and foreign governments under special agreements or arrangements, provided those governments keep the information confidential. Like TSCA, CEPA does not generally mandate or encourage public disclosure of information not deemed confidential.[130]

D. Kid Safe Chemicals Act (KSCA)

First introduced in 2005, the Child, Worker, and Consumer-Safe Chemicals Act, or the "Kid Safe Chemicals Act" (KSCA), would amend TSCA by adding a new chapter titled "Title V – Child Safe Chemicals". KSCA's stated goal is to "eliminate the exposure of all children, workers, consumers, and sensitive subgroups to harmful chemicals distributed in commerce by 2020."[131] In June 2007, environmental health and justice advocates from across the country developed a revised version of KSCA, which incorporates additional policy concepts not included in the original legislation. In May 2008, KSCA was reintroduced with some modifications, including some of the proposals set forth in the June 2007 revise.[132]

This section discusses all three KSCA proposals, beginning with KSCA 2005, proposed changes in the revised KSCA 2007, and changes to KSCA 2005 now found in KSCA 2008.

The main provisions of KSCA 2008 require U.S. EPA to:

- Identify the highest priority chemicals for review by 2009;
- Make safety determinations for at least 300 priority chemicals by 2012 and ban or restrict the use of a chemical if it cannot meet the safety standard;
- Make safety determinations for all remaining chemicals by 2020 and ban or restrict the use of a chemical if it cannot meet the safety standard; and
- Encourage the replacement of harmful chemicals with safer alternatives.

i. *KSCA 2005*

Data Requirements
Within one year of enactment of KSCA, each chemical manufacturer must submit a statement signed by its chief executive officer to U.S. EPA indicating whether, based on available information, its chemical meets the safety standard described below or insufficient data exist to determine whether the chemical meets the safety standard. In addition, the manufacturer must provide all "reasonably available information in the company's possession or control" regarding: (1) the physical, chemical, and toxicological properties of the chemical; (2) the annual production volume and known uses of the chemical; and (3) exposure and fate information related to the chemical. Manufacturers must update this information at least every three years and at any time at which significant new information becomes available. U.S. EPA has broad authority to request any additional information from a chemical manufacturer that is necessary for it to determine whether the safety standard has been established.

KSCA provides that U.S. EPA must establish a minimum set of data requirements to ensure that safety determinations are based on reliable data. The agency may establish a tiered process for the submission of data by manufacturers.

Prior to a new chemical being distributed in commerce, the manufacturer must provide to U.S. EPA the same information described above.

Data Reliability and Verification
At least once per year, U.S. EPA must randomly inspect at least three percent of the commercial and private laboratories that develop the data required to be submitted by manufacturers. Annually, U.S. EPA must perform a comprehensive data audit on a statistically significant number of data submissions submitted by manufacturers.

Priority List and Safety Standard
KSCA requires U.S. EPA to create and maintain a priority list of at least 300 chemicals within eighteen months after the date of enactment. In creating the list, U.S. EPA must take into account whether the chemical: (1) is found in biomonitoring studies; (2) is found in food or drinking water; (3) is manufactured or discharged into the environment at a volume of more than one million pounds annually; (4) is a known or suspected reproductive, neurological, or immunological toxicant, carcinogen, mutagen, or endocrine disruptor, or causes negative developmental effects; or (5) is persistent or bioaccumulative. U.S. EPA must add to the priority list of chemicals at least annually until all chemicals that meet any one of these five criteria have been added to the list.

KSCA establishes a safety standard with respect to chemicals. To meet the safety standard (or "safe" level) for adults, there must be "a reasonable certainty that no harm will be caused by aggregate exposure of a fetus, infant, child, worker, or member of other sensitive subgroup" to the chemical in question. For fetuses, infants, and children, the safety standard must account for their special vulnerability to potential pre- and post-natal exposures by applying an additional ten-fold safety factor to the level established for adults. The "reasonable certainty of no harm" standard comes from the Food Quality Protection Act of 1996 (FQPA), which means a one in one million cancer risk to the most vulnerable person in the population, and for non-cancer effects, exposure must be 1,000 times less than the level that causes no adverse effects in animal studies.

Manufacturers bear the burden of demonstrating that their chemicals meet the safety standard. Under KSCA, U.S. EPA must determine whether a chemical manufacturer has established that its chemical on the priority list meets the safety standard within three years of a chemical's placement on the list. Within fifteen years of the enactment of KSCA, U.S. EPA must determine whether manufacturers have met the safety standard for all remaining chemicals in commerce. U.S. EPA must reassess the safety of chemicals distributed in commerce at least once every fifteen years.

In determining whether the safety standard is met, U.S. EPA must take into account: (1) environmental fate and transport of the chemical; (2) biological fate and transport of the chemical; (3) acute, subchronic, and chronic human health effects of exposure to the chemical, including reproductive, developmental, genotoxic, neurotoxic, immunotoxic, and endocrine-disrupting effects; (4) potential for additive or synergistic effects to result from exposure to multiple chemicals; (5) ecotoxicty of a chemical to avian, terrestrial, and aquatic species; (6) the presence of the chemical in human blood, fluids, or tissue, and in food or drinking water; and (7) uses of the chemical and associated known and potential releases and exposures.

Prohibition on Manufacture of Chemical

If a chemical manufacturer fails to provide any required data or additional information requested by U.S. EPA, the chemical cannot be manufactured. If U.S. EPA determines that a chemical fails the safety standard, it cannot be manufactured.

In addition, if U.S. EPA fails to: (1) determine whether a chemical has met the safety standard within five years of the chemical's placement on the priority list, or (2) determine whether any of the remaining chemicals have met the safety standard within the requisite timeframe, the chemical cannot be manufactured or distributed in commerce.

Within ninety days of enactment of KSCA, new chemicals will be banned from manufacture unless they meet the safety standard.

Exemptions to Prohibition

Exemptions to a prohibition on the manufacture of a chemical for up to five years (with the possibility of renewal in five year increments) can be granted by the President of the United States, as a non-delegable duty, in the interest of national security, to avoid disruption to the national economy, or if "no feasible alternative for the specified use of the chemical substance is available".

U.S. EPA may also allow a chemical to be manufactured for a specified use if the agency determines the use meets the safety standard.

Safer Alternatives

Within a year after enactment of KSCA, U.S. EPA must establish a program to create market incentives for the development of safer alternatives to existing chemicals. The program would include expedited review of a new chemical for which the manufacturer submits an alternatives analysis indicating that the new chemical is a safer alternative for a particular use over an existing chemical used for the same purpose.

Public Access to Information

Under KSCA, U.S. EPA must make available to the public: (1) any information provided to the agency related to the properties and hazards of a chemical, and (2) any "nonconfidential information" provided to the agency related to exposure to the chemical.

If a chemical manufacturer submits to U.S. EPA any confidential business information, the chief executive officer must provide a written justification for maintaining the confidentiality of the information and certification that the information is not otherwise publicly available. KSCA specifically indicates that the "name of a chemical substance and all information concerning its effects on human health or the environment shall not be considered to be confidential business information."

Cost of Regulatory Program
Chemical manufacturers must pay for the costs associated with certifying that their chemicals meet the safety standard and providing any additional data requested by U.S. EPA. Taxpayer dollars presumably would pay for the reviews and determinations conducted by the agency without support from fees imposed on manufacturers.

ii. KSCA Proposed Revisions 2007

In June 2007, environmental health and justice advocates from across the country prepared a revised version of KSCA. The main additional policy concepts not included in the original legislation are described below.

Identification of Chemicals
One such addition requires U.S. EPA, within five years of enactment of KSCA, to identify all chemicals distributed in commerce that: (1) are PBTs or vPvBs, (2) meet one or more of the criteria used to identify chemicals to be added to the priority list, (3) for which information is insufficient to determine whether the chemical is a PBT or vPvB or meets any of the criteria, and (4) for which sufficient information exists for U.S. EPA to determine that the chemical is not PBT, vPvB, or toxic. One-fifth of chemicals in commerce must be evaluated each year for possible identification.

Data Requirements
The revised KSCA provides much greater detail on the data required for submission by chemical manufacturers to U.S. EPA along with a more detailed timeframe for when the data should be provided. It also provides for the submission of the data to all known downstream users of the chemical.

Data Reliability
Additional provisions in the revised KSCA related to data reliability require U.S. EPA to establish and maintain a registry of all health and safety related studies initiated in response to data requirements or information requests to ensure that methods used and results of the studies are reported.

Priority List
The revised KSCA provides for nominations to the priority list of chemicals by members of the public. It also directs U.S. EPA to focus first on chemicals that show evidence of both hazard and exposure when populating the priority list. It also requires U.S. EPA to take into account all *available information* in determining the priority list and in making safety determinations.

Presumptive Ban on Certain Chemicals
The revised KSCA also requires the Centers for Disease Control and Prevention (CDC) to conduct a biomonitoring study to determine the presence of chemicals in human cord blood. Any chemical identified by U.S. EPA that meets one of the criteria set forth in the identification

process *and* that is found in the CDC biomonitoring study will be presumed to have failed the safety determination and be restricted for distribution in commerce.

Alternatives Assessment and Safer Alternatives
The revised KSCA includes some language providing for an alternatives assessment. Specifically, it authorizes U.S. EPA to: (1) require chemical manufacturers to produce information sufficient to determine whether a safer alternative to a chemical is available, (2) require downstream chemical users to prepare an assessment of the availability of safer alternatives, and (3) require any manufacturer or downstream user to submit an itemized description of all uses of a chemical. U.S. EPA may require a transition to identified safer alternatives. Companies and the public can petition U.S. EPA to prohibit a specified use of a chemical based on a showing that safer alternatives are available for such use.

Public Access to Information
The revised KSCA expands on the public's access to information, creating a requirement that public access include an internet-accessible database. The process for designating information as confidential business information also is more clearly spelled out under the revised KSCA.

Legacy Chemicals
To address legacy chemicals that continue to cause harm to people and the environment, the revised KSCA includes a provision to fund work to develop technologies and methodologies to identify, measure, reduce, and mitigate exposures to toxic chemicals caused by prior industrial, consumer, or commercial activity.

iii. KSCA 2008

In May 2008, KSCA was reintroduced in the 110th Congress.[133] The main provisions that changed from KSCA 2005 are described below.

Data Requirements
KSCA 2005 provided that U.S. EPA must establish a minimum set of data requirements to ensure that safety determinations are based on reliable information. KSCA 2008 includes the same directive but gives the agency a deadline for establishing the minimum set of data requirements—180 days after enactment. KSCA 2008 also provides that the requirements should ensure that safety determinations are based on sufficient data.

KSCA 2008 also details guidelines for the minimum set of data requirements. At the least, the minimum data requirements must require the submission of information sufficient to determine whether a chemical has the potential to: (1) persist or bioaccumulate in humans or nonhuman organisms; (2) cause skin irritation or skin sensitization; (3) cause mutations, cytogenicity, or chromosomal aberrations; (4) cause acute or chronic toxicity in humans; (5) cause reproductive or developmental toxicity in humans; (6) cause acute or chronic toxicity in aquatic organisms; (7) persist in the environment; or (8) degrade into substances that have the potential to exhibit any of these effects.

The data requirements also must include: (1) information on production, processing, use, and exposure-related information; (2) an assessment of the number of workers reasonably likely to be exposed to the chemical at the site of manufacture; and (3) a description of the commercial and consumer uses of the chemical.

Data Reliability and Verification
U.S. EPA must establish and maintain a registry of all health and safety related-studies initiated in response to KSCA 2008 data requirements or requests by U.S. EPA to ensure that results of all initiated studies are reported and made available to the agency, along with details of the method utilized in each study.

Categorization of Chemicals
Within five years of enactment, KSCA 2008 requires U.S. EPA to categorize all chemicals distributed in commerce according to whether they meet any of the criteria for listing on the priority list and whether information is insufficient to determine whether the chemical meets any of the criteria. This categorization process would be based on existing information available to U.S. EPA. The categorization would be published in the Federal Register.

Priority List and Safety Standard
KSCA 2005 did not specify the number of chemicals required to be added to the priority list each year by U.S. EPA. KSCA 2008 requires U.S. EPA to add at least 200 chemicals to the priority list annually until all chemicals that meet any of the criteria for listing have been added. KSCA 2008 also includes a new provision that enables any individual or entity to petition U.S. EPA to add a specified chemical to the priority list, giving U.S. EPA the authority to decide whether to add the nominated chemical. KSCA 2008 includes additional criteria for determining whether to add a chemical to the priority list. The additional criteria include whether the chemical: (1) is found in indoor air, or (2) possesses other toxicological properties of concern (defined as "actual or potential toxicity, bioconcentration, or other biological or adverse effects of a chemical substance").

In determining whether the safety standard is met, KSCA 2008 requires U.S. EPA to take additional factors into account, including the: (1) presence of the chemical in indoor air, (2) potential effects of the chemical from low-dose exposures, (3) timing of exposure during sensitive stages of human development, and (4) size, shape, and surface properties, and any other physical characteristics, of the chemical that may effect the toxicity, hazards, or exposure of the chemical.

Under KSCA 2008, a chemical will be presumed to fail the safety standard if the chemical: (1) is persistent or bioaccumulative, or is a known or suspected reproductive, neurological, or immunological toxicant, carcinogen, mutagen, or endocrine disruptor, or causes negative developmental effects or has other toxicological properties of concern; and (2) is found in human cord blood. The presumption may be rebutted if U.S. EPA determines that the chemical meets the safety standard.

KSCA 2008 allows U.S. EPA to reassess a chemical that the agency previously determined met the safety standard, if new information raises a credible question as to whether the chemical continues to meet the safety standard.

Prohibitions on Chemicals
Generally, the provisions in KSCA 2005 that provide for a ban on the manufacture of a chemical were expanded in KSCA 2008 to include a ban on the manufacture, importation, and distribution of the chemical.

Whereas KSCA 2005 provided that the manufacturing of a chemical would be prohibited if U.S. EPA failed to determine whether a chemical met the safety standard within a specified timeframe, KSCA 2008 removes this provision.

U.S. EPA may prohibit a specified use of a chemical in consumer products if the agency determines that the use of the product in the home results in human exposure that does not meet the safety standard.

Exemptions to Prohibition
Under KSCA 2008, use exemptions only may remain in effect for five years, with the possibility of renewal in additional five year increments.

Public Access to Information
KSCA 2008 specifically provides that the information available to the public be accessible via an internet-accessible database.

Within one year of enactment, KSCA 2008 requires U.S. EPA to establish standards specifying acceptable bases for classifying information as CBI and documentation that must accompany the request to designate information as CBI.

Within ninety days of the submission of a request to designate information as CBI, U.S. EPA must review the request and decide whether to accept or reject the request. If such a request is accepted, the designation would remain in effect for five years, at which time the company could submit a new request for confidentiality.

CBI must be made available to state, tribal, and municipal governments.

E. SAFER Model Policy

The State Alliance for Federal Reform of Chemicals Policy (SAFER) is a coalition of state organizations whose goal is to pass comprehensive chemicals policy reform measures in key states to help prompt reform at the federal level. Over the last three years, SAFER has worked to develop a model policy for states to implement as part of this effort.

Core to SAFER's model policy is the idea that chemicals of highest concern should be substituted for use with safer alternatives as they become available. This approach can be contrasted with KSCA, which restricts chemicals of high concern from use but allows for exemptions to this ban for specified uses if feasible alternatives do not exist. The nuanced distinction is important to understand. Under SAFER's model policy, a chemical would not be phased out until a safer alternative is identified. Under KSCA, a chemical would be restricted from use if it fails the safety test, but specified uses of the chemical can be given exemptions to the restriction for up to five years (with the possibility of renewing the extension) if no feasible alternative exists.

Chemicals Categorization
SAFER's model policy requires the appropriate state agency to prepare and publish a Chemicals Categorization List within one year of enactment. The list would assign either (1) every chemical used in the state, or (2) some subcategory of chemicals used in particular industries or products, to one of four levels of concern:

- Tier 1: chemicals of high concern (defined as a chemical known or likely to be a carcinogen, mutagen, reproductive or developmental toxicant, neurotoxicant, endocrine disruptor, or of equivalent concern in humans; a highly persistent, highly bioaccumulative, and toxic chemical; a very persistent and very bioaccumulative

chemical; a very persistent and toxic chemical; or a very bioaccumulative and toxic chemical);
- Tier 2: chemicals of concern (defined as a chemical for which there is suggestive evidence, including modeling data, that the chemical is a carcinogen, mutagen, reproductive or developmental toxicant, neurotoxicant, endocrine disruptor, or of equivalent concern in humans; a moderately persistent, bioaccumulative, and toxic chemical; a moderately persistent and toxic chemical; or a moderately bioaccumulative and toxic chemical);
- Tier 3: chemicals of unknown concern (defined as a chemical for which reasonably available data, surrogate measures, and modeling results are insufficient to determine whether the chemical could or should be classified as a Tier 1 or Tier 2 chemical); and
- Tier 4: chemicals of lower concern (defined as a chemical that does not qualify as a Tier 1, 2, or 3 chemical, has not been listed as a high priority chemical by another governmental authority, and is readily biodegradable).

This list must be updated at least every four years to incorporate new scientific information and data.

The assignment of a chemical to a tier would be based on: (1) prior work by an authoritative body that has characterized chemicals, including, but not limited to, California's Proposition 65 list, the Canadian Domestic Substances List, and the International Agency Research on Cancer's list of carcinogens; and (2) "readily available data, surrogate measures, and modeling results on the inherent hazardous properties of chemical substances".

In assigning a chemical to the Chemicals Categorization List, a chemical must be placed in the highest tier for the endpoint of highest concern.

Chemical Action Plans

Within eighteen months of the appropriate state agency's identification of a Tier 1 chemical, the agency must establish a Chemical Action Plan for the chemical. Among other things, the plan must include:

- Timetables, schedules, and deadlines for achieving substitution of the Tier 1 chemical with safer alternatives;
- Requirements for all legal entities using a Tier 1 chemical in the state to create a Substitution Plan to demonstrate how the entity will substitute all uses of the Tier 1 chemical with safer alternatives; and
- Priorities for state agency action.

Safer alternatives include changes in chemical, material, product, process, function, system, or any other action whose adoption would reduce the potential for harm.

If the state agency determines that safer alternatives are feasible and of comparable cost, the agency would be required to set and enforce deadlines within one year for certifying the substitution of safer alternatives. If the state agency determines that safer alternatives are feasible but require extensive capital expenditure or training, the state agency must implement a business assistance or employee transition program and set a timetable for completing substitution as expeditiously as possible. If the state agency determines that safer alternatives are not feasible, the Chemicals Action Plan must designate research and development activities to be pursued. Private entities would be encouraged to conduct the research and development.

Substitution Plans
Two years after a chemical is identified as a Tier 1 chemical, all manufacturers, importers, and downstream users of the chemical must submit to the appropriate state agency a Substitution Plan. The plan must include:

- Identification of all uses of each Tier 1 chemical;
- Identification of all alternatives to each Tier 1 chemical;
- Assessment of alternatives based on costs and performance;
- Identification of preferred alternatives;
- Timetables, schedules, and deadlines for implementing the preferred alternatives; and
- Metrics for measuring and assuring the full substitution of each Tier 1 chemical use.

Use Data Collection
Within twelve months after the appropriate state agency categorizes a chemical as Tier 1, the chemical may not be sold, used, or distributed in the state unless the manufacturer of consumer products containing the chemical provides the following information:

- Name of the chemical and its Chemical Abstracts Service Registry Number;
- Brief description of the product containing the chemical;
- Description of the function of the chemical in the product;
- Indication of the amount of the chemical used in each unit of the product;
- Total amount of the chemical in all units of the product sold in the state during the most recent calendar year; and
- Name and address of the manufacturer along with the name of a person serving as the point of contact.

A trade association representing downstream users may act to fulfill the responsibilities of individual users. Downstream users also may supply the required information for a product category rather than an individual product.

Hazard Data Collection
Within twelve years of enactment, the appropriate state agency would have the authority to require additional hazard data for chemicals in Tier 3.

VI. CALIFORNIA MUST DEVELOP A UNIQUE CHEMICALS POLICY FRAMEWORK

The chemicals policy frameworks discussed above represent a shift—in some cases, a significant one—from the TSCA-style approach to regulating chemicals. None of the frameworks, however, incorporates all of Environment California Research & Policy Center's core principles for chemicals policy reform. This section briefly evaluates the extent to which the different frameworks reflect our core principles and concludes that California must develop its own hazard-based framework.

While Canada recently designated bisphenol A, a developmental, neural, and reproductive toxicant commonly used in plastic and epoxy resins, as "toxic" under CEPA—a decision receiving much attention in the environmental health community—the CEPA framework does not diverge from TSCA in a significant enough way to provide much guidance for chemicals policy reform. The categorization of Domestic Substances List chemicals is useful to the extent significant information exists about a chemical, but this process and other CEPA-assessments do little for chemicals about which the government knows very little and even those categorized as anything less than high priority (e.g., medium priority chemicals, which will be addressed through performance agreements with industry). CEPA has resulted in limited action to restrict or ban chemicals known to be hazardous. On the whole, CEPA fails to incorporate our core principles and fails to provide a good model for California.

Like TSCA, most of the alternative chemicals policy frameworks rely on risk assessment as the method for evaluating the safety of a chemical. As described in greater detail in section IV of this report, their reliance on risk assessment is problematic. Because there is incomplete and inadequate information on many hazard traits, risk assessments will be made without sufficient information. Even under REACH, the data requirements do not include all of the health endpoints of concern. More importantly, no framework's data requirements recognize the need to develop new testing methods or acknowledge that testing methods need to evolve over time to reflect new advancements in science. This does not mean that we need to wait until new testing methods are developed before requiring data to be produced. Rather, a determination should be made about the best available test for any given hazard trait, and hazard data should be produced utilizing this method. Simultaneously, new testing methods should be developed for those hazard traits for which there are inadequate or no current testing methods.

In addition, traditional risk assessment does not factor in new concepts in science such as low-dose effects, timing of exposure, cumulative impacts, and synergistic effects. Although KSCA proposes to incorporate a couple of these concepts into the type of risk assessment the policy contemplates, it is not clear in the legislation how that will happen in practice such that the risk assessments actually differ in a meaningful way from traditional risk assessment. A comprehensive chemicals policy needs to provide clear guidance for how government is to engage in a different type of analysis incorporating such concepts.

Although SAFER's model policy embraces a hazard-based approach, the policy represents more of a "bad actor chemicals" program that seeks to eliminate the top tier of priority hazardous chemicals. As noted previously in this report, such programs are critical for reducing immediate exposures to harmful chemicals. The model policy does not provide, however, sufficient guidance on how to develop a more comprehensive hazard-based approach to assessing the safety of all chemicals in use or proposed for use.

Notwithstanding their reliance on risk assessment, the REACH and KSCA frameworks represent a significant departure from the traditional burden placed on government to determine whether a chemical is safe. These two frameworks shift the burden to industry to demonstrate the safety of their chemicals. This type of burden shifting is consistent with our core principles and critical for a comprehensive chemicals policy.

Each of the alternative chemicals policy frameworks includes provisions to prohibit the manufacture and use of specified categories of hazardous chemicals, with some exceptions to the ban. Both KSCA and REACH presumptively ban certain chemicals based on their hazard traits, but exemptions to the ban are permitted if the chemical or specified uses are shown to be "safe" as determined through a risk assessment. SAFER's model policy bans hazardous chemicals but only does so if a safer alternative exists.

Under none of the frameworks does industry bear the full cost of manufacturing or using a hazardous chemical. Even with frameworks that require industry to prove a chemical's safety, exemptions to bans or restrictions permit chemicals that are hazardous to remain on the market with no fee associated with the continued use of that substance.

SAFER's model policy embraces the concept of safer alternatives by requiring the most hazardous chemicals to be replaced with safer substitutes. Under the model policy, however, an alternative actually does not have to be "safer". If there are inadequate data on the safety of a chemical, it still would be considered safer than a top tier hazardous chemical even though it may actually be relatively more harmful. In addition to potentially causing exposures to more harmful chemicals, this reinforces the incentive that currently plagues TSCA not to produce data. Moreover, the model policy only provides for the elimination of a hazardous chemical if a feasible substitute is available. KSCA 2008 is a weak attempt to incorporate the concept of safer alternatives by mandating the establishment of a program to create market incentives for the development of safer alternatives; it includes no mandate that companies move toward the use of safer substitutes.

Finally, under REACH and KSCA, information relating to the health and safety impacts of a chemical cannot be considered confidential business information. KSCA 2008 goes further by requiring that such information be available to the public via an internet-accessible database. In addition, KSCA 2008 requires U.S. EPA to make an affirmative decision to approve CBI requests by companies, and CBI designations remain in effect for only five years before a company needs to submit a new request for its continued designation as CBI. Surprisingly, REACH treats some information, including the precise use or application of a chemical, as confidential business information, even if a company does not claim such information as confidential.

While REACH, KSCA, and the SAFER model policy each contain elements that help inform the ideal comprehensive chemicals policy, none of these alternative frameworks serve as a model that incorporates Environment California Research & Policy Center's core principles for a comprehensive chemicals policy. Neither of the most comprehensive policies analyzed—KSCA and REACH—incorporates a policy solution that embraces the alternative paradigm proposed in this report. The focus of SAFER's model policy on high hazard chemicals also limits its usefulness in crafting a comprehensive chemicals policy. Although the state can certainly draw on some of the elements from these alternative policies and the critical thinking that went into their development, California must commit to establishing a comprehensive, hazard-based approach to assessing chemicals in order to fully protect human health and the environment.

VII. CONCLUSION

When it comes to environmental policy, California undoubtedly leads the country. Not only do California policymakers often set the terms of the debate, they draw on a diversity of interests to develop bold initiatives.

Through the Green Chemistry Initiative, California has the opportunity to implement meaningful chemicals policy reform. Particularly compared to other states, California has the capacity to create a market for green chemicals through a variety of regulatory mechanisms, including restrictions and prohibitions on hazardous chemicals, the development of the necessary infrastructure to promote a green chemicals economy, and requirements for complete health and safety information for all industrial chemicals.

California must establish a comprehensive program that provides for the collection and evaluation of health and environmental impacts data, ensures that chemicals known or suspected of causing harm or for which data do not exist to make such a determination are restricted or prohibited from use, and incorporates safer substitution policies that drive businesses to create and use safer chemicals or practices. By making all health and safety data publicly available and establishing transparent and open decision-making processes, businesses will be better able to make informed decisions about chemical use and the public will have critical information about potential toxic threats and safer choices in the marketplace and have an opportunity to participate in decisions affecting their health and the health of the environment.

Environment California Research & Policy Center urges Governor Schwarzenegger and California policymakers to again lead the way on environmental policy by embracing meaningful, comprehensive chemicals policy reform.

VIII. APPENDIX

A. California Environmental Protection Agency BDO Descriptions[134]

CalEPA Mission
The mission of the California Environmental Protection Agency (CalEPA) is to restore, protect, and enhance the environment, to ensure public health, environmental quality, and economic vitality.

Following are the missions of the boards, departments, and offices that make up CalEPA:

Air Resources Board
The Air Resources Board's mission is to promote and protect public health, welfare, and ecological resources through the effective and efficient reduction of air pollutants in recognition and consideration of the effects on the economy of the state.

Department of Pesticide Regulation
The Department of Pesticide Regulation has the primary responsibility for regulating all aspects of pesticide sales and use to protect the public health and the environment. DPR's mission is to evaluate and mitigate impacts of pesticide use, maintain the safety of the pesticide workplace, ensure product effectiveness, and encourage the development and use of reduced risk pest control practices while recognizing the need for pest management in a healthy economy.

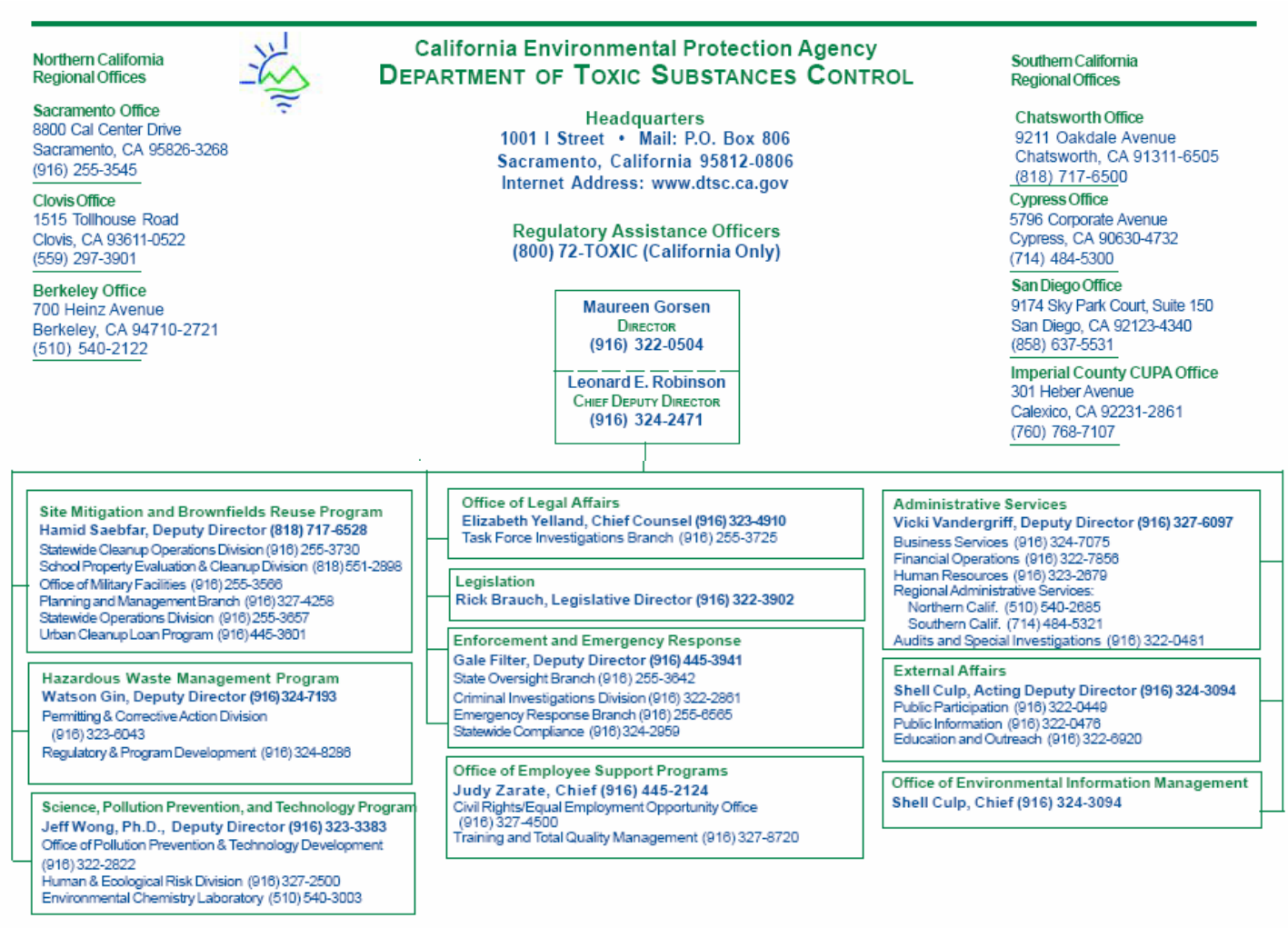
Department of Toxic Substances Control
The mission of the Department of Toxic Substances Control is to restore, protect, and enhance the environment, to ensure public health, environmental quality, and economic vitality, by regulating hazardous waste, conducting and overseeing cleanups, and developing and promoting pollution prevention.

Integrated Waste Management Board
The mission of the Integrated Waste Management Board is to protect the public health and safety and the environment through waste prevention, waste diversion, and safe waste processing and disposal.

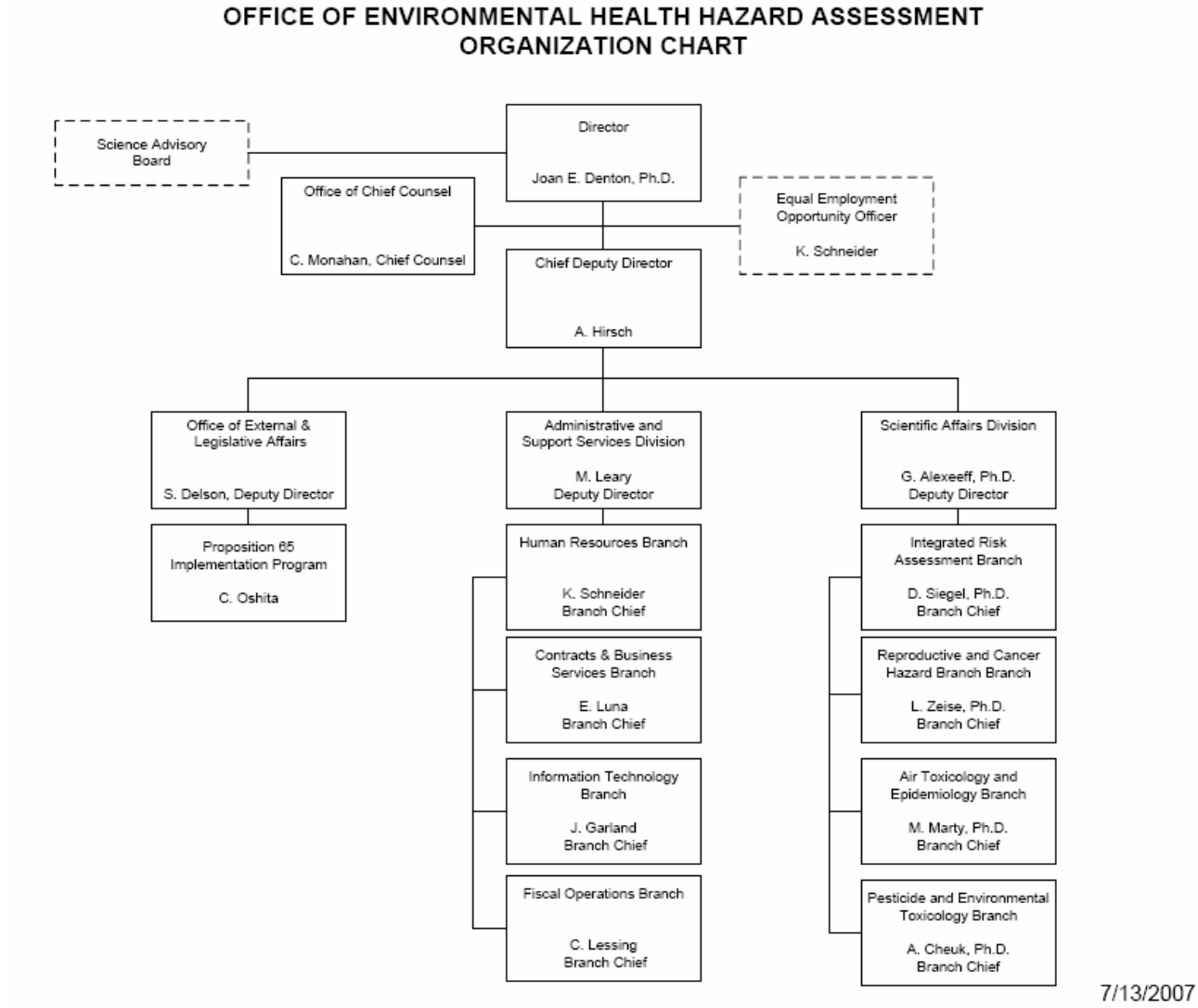
Office of Environmental Health Hazard Assessment
The mission of the Office of Environmental Health Hazard Assessment is to protect and enhance public health and the environment by objective scientific evaluation of risks posed by hazardous substances.

State Water Resources Control Board
The State Water Resources Control Board's mission is to preserve and enhance the quality of California's water resources, and ensure their proper allocation and efficient use for the benefit of present and future generations.

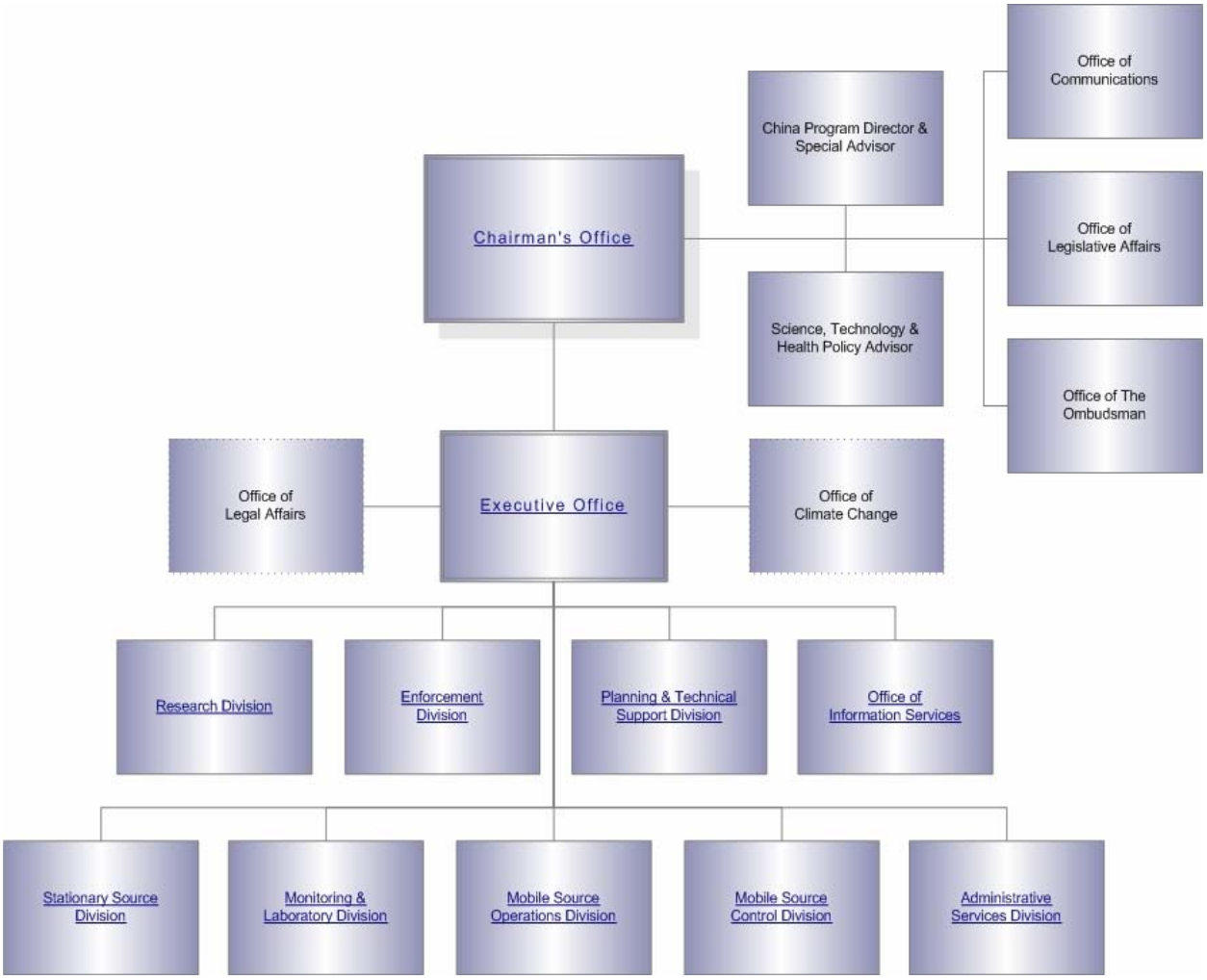
B. California Department of Toxic Substances Control Organizational Chart[135]



C. California Office of Environmental Health Hazard Assessment Organizational Chart[136]



D. California Air Resources Board Organizational Chart[137]



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[114] Nicole Davidson, *Results of Canadian Ecological Categorization of the DSL and Next Steps*, GLBTS Integration Workgroup Meeting, May 18, 2006.
[115] Richard Denison, Environmental Defense, *Highlights of Canadian Industrial Chemicals Policy*, Power Point Presentation to CHANGE coalition, November 28, 2006.
[116] *See supra* note 96.
[117] *See supra* note 115.
[118] *See supra* note 96.
[119] *Id.*
[120] *Id.*
[121] *Id.*
[122] *Id.*
[123] *See supra* note 115.
[124] *See supra* note 96.
[125] *Id.*
[126] *Id.*

[127] *Id.*
[128] *Id.*
[129] *Id.*
[130] *Id.*
[131] Child, Worker, and Consumer-Safe Chemicals Act of 2005, S. 1391, 109th Cong. (2005); Child, Worker, and Consumer-Safe Chemicals Act of 2005, H.R. 4308, 109th Cong. (2005) ("Kid Safe Chemicals Act").
[132] *See* Child, Worker, and Consumer-Safe Chemicals Act of 2008, H.R. 6100, 110th Cong. (2008) ("Kid Safe Chemicals Act").
[133] *See id*.
[134] Cal/EPA Mission, last updated January 19, 2007, http://www.calepa.ca.gov/About/mission.htm.
[135] California Department of Toxic Substances Control Organizational Chart, updated February 8, 2008, http://www.dtsc.ca.gov/ContactDTSC/upload/FLY_OEA_OrgChart.pdf.
[136] California Office of Environmental Health Hazard Assessment Organizational Chart, July 13, 2007, http://www.oehha.ca.gov/about/OrgChart.pdf.
[137] California Air Resources Board Organizational Chart, last updated November 8, 2007, http://www.arb.ca.gov/html/org/org.htm.