

## ***CHANGE Framework with more detailed analysis***

### **DATA COLLECTION AND USE INFORMATION**

#### ***Matrix***

California should develop a matrix that compiles hazard trait information. The information must be understandable to key audiences that include state agencies, businesses, workers, and the public.

The matrix should allow for inclusion of information about all chemicals in use or proposed for use. The matrix should also include “spaces” for all of the hazard traits for each chemical and explicitly show where data are missing.

The state should include data that it views as credible and appropriate to represent the hazard trait.

#### ***Requirements for production and compilation of data***

The State of California should establish data requirements that ensure the state and other interested parties, such as businesses and consumers, are able to obtain information about the safety and use of a chemical.

The hazard and use data should be publicly available and verifiable. Such data should not be considered confidential business information.

#### **Hazard data**

The state should obtain all available, credible, and reliable data to complete the matrix and to support comprehensive assessment of chemical hazards. Some of the data will be accessible through REACH submissions. The state should establish a partnership with the EU to gain access to the data that is submitted and consider such data, if appropriate, for inclusion in the matrix. The state also should consider cooperating with other governmental entities, including other states and foreign governments, to obtain additional data to add to the matrix. The state should require manufacturers or users of chemicals to provide or generate missing data according to an established timeline.

The data set should include information necessary to determine: (A) the impact of the physical properties of chemicals, including flammability and corrosiveness, and (B) the potential of a chemical to cause morbidity or mortality, and specifically, any of the following health or environmental impacts:

- 1) Mutagenicity and genetic toxicity;
- 2) Reproductive effects, including alterations in fertility and birth outcomes such as birth weight and gestational age;
- 3) Developmental toxicity, including abnormalities present at birth or that manifest later, and effects on development, including, but not limited to, reproductive, metabolic, motor or cognitive effects that result from exposure at any developmental stage;
- 4) Cancer;

- 5) Immunological effects including allergic sensitization;
- 6) Neurological and neurodevelopmental effects;
- 7) Effects on organs such as liver, kidney, eye, bone marrow, lungs, and heart;
- 8) Respiratory effects;
- 9) Endocrine disruption;
- 10) Other disruptions or perturbations of signaling and hormone systems;
- 11) Epigenetic effects;
- 12) Persistence;
- 13) Propensity to bioaccumulate;
- 14) Acute or chronic toxicity in aquatic or terrestrial organisms and wildlife; and
- 15) Potential to degrade into substances that may exhibit any of the effects listed above.

In enacting the data requirements with respect to these hazard traits, we believe definitions for these traits should be included in a statute with as much specificity as possible.

The state also should have broad authority to request additional data based on preliminary testing results or emergence of new information. The state should also be able to waive additional testing in cases where it is unnecessary for establishing hazard (i.e. for those chemicals that have well established hazards).

#### Use and other data

The state should establish mandatory data reporting requirements about uses of chemicals in products and processes and chemicals in the waste stream (including from packaging disposal, manufacturing, and the product itself). Specifically, producers, users and importers of chemicals should be required to report on a regular basis chemical production, processing, use, and exposure information.

Information that chemical producers should provide includes, but should not be limited to:

- 1) The distribution of the substance in commerce in California (i.e., the portion that is used in industrial processes, the portion introduced into products, and the portion shipped out-of-state),
- 2) The environmental fate of the substance (i.e., air, water, deep well injection, product waste, etc.), and
- 3) The estimated number of workers likely to be exposed to the chemical in industrial processes, through commercial use of products, or in transfer and handling.

Information that Manufacturers (by detailed NAICS code) should provide includes, but should not be limited to:

- 1) The volume of the substance purchased, stored on-site, used in industrial processes, introduced into chemical products, and dispersed into environmental media,
- 2) The maximum concentration of the substance when used in chemical products,
- 3) The proportion of sales of chemical products purchased by commercial entities for use by workers versus the sales of products on the consumer market, and  
The estimated number of workers likely to be exposed to the chemical in industrial processes, through commercial use of products, or in transfer and handling.

***Determine best available testing methods to ascertain hazard traits and develop improved methods***

OEHHA should determine the best testing methods currently available to be used to ascertain the hazard traits and other characteristics. For some hazard traits, current testing methods may be insufficient. Notably, for some of the hazard traits and other characteristics, the current testing methods are outdated. Many methods first adopted in the 1970s are still in use. Methods may not address all of the aspects of a hazard trait. Methods may be time-consuming.

The public interest will be served by the development of new methods that can accurately predict a chemical's hazard traits or a chemical's ability to cause biological changes that are likely to lead to hazard traits and diseases, and that may be more efficient or most cost-effective. However, the determination of what constitutes an acceptable method for a hazard trait must be made through a scientifically-based process that is conducted without conflicts of interest and allows validation from exiting methods. Accordingly, OEHHA should lead a process, with input from other CalEPA BDOs, that assists in the development of new testing methods that, among other things, incorporate the importance of low doses and the significance of background exposures, synergistic effects, and the timing of exposures during the life cycle; and address the effects of cumulative exposures and differences in genetic responses to chemical exposure.

CalEPA and its BDOs, with OEHHA leading the scientific aspects, should invest its own resources and partner with outside academic and government agencies to develop improved testing methods. Funding must be made available to support this.

***Providing data on chemical combinations***

In addition to having information about the hazard traits of chemicals, many consumer products contain several chemicals used in combination. These combinations also are rarely tested for their effects on human health and the environment. The tests that are conducted are not released to either the public or to state officials. As the state begins to collect information about individual chemicals through the above described data collection program, it should introduce a program to mandate hazard testing on chemical-intensive consumer products such as cleaning products, household and commercial solvents, and personal care products. This information also should be in a searchable database to ensure that consumers, downstream users, workers, and state agencies have the ability to compare products and take action when necessary.

***Ensure valid and reliable data***

In addition to establishing the testing methods that are acceptable to provide data relevant to each of the hazard traits and any other parameters, the state will need to develop procedures that ensure that data provided are reliable and valid. This is an issue that has been widely recognized to be challenging due to the variety in testing methods that may be used, the varying sources of these methods, and the different kinds of laboratories that could potentially be involved, including academic labs funded by research grants, commercial laboratories, government laboratories, and laboratories that are run by companies that manufacture and use chemicals. No single set of procedures is likely to be applicable to all of these entities or to every test. Rather, a process for establishing the qualification of laboratories to conduct tests and for verification will be needed. This may rely on existing procedures to the extent that they are credible and

available, such as existing certification procedures but will also likely require oversight by an expert panel constituted without conflicts of interest.

### ***Timing and prioritization for data submission***

With tens of thousands of chemicals in use, the state likely will need to prioritize chemicals for data submission. We believe the highest priority chemicals should include: 1) chemicals manufactured or imported in the United States at a volume of 1 million pounds or more per year, 2) chemicals already known to be persistent or bioaccumulative, and 3) chemicals that have been detected in people, either as parent chemicals or as metabolites. Additional chemicals that should be prioritized include those that demonstrate the potential for harm to human health or the environment based on other types of screening methods. Initial data on these chemicals should be required to be provided to the state within three years.

Within ten years, however, data on all chemicals should be required to be provided to the state.

## **ECONOMIC INCENTIVES AND MARKETS**

In order for the Green Chemistry Initiative to be successful, California must create both positive incentives for desirable results and disincentives for undesired practices, including penalties where appropriate.

To create a disincentive to use untested or hazardous chemicals, the State of California should assess fees on products or processes for which there is no or inadequate information about hazard traits or other health and safety information or for the use of hazardous chemicals in products.

The Green Chemistry Initiative should mandate that companies that make or sell products in California containing hazardous chemicals must take them back at the end of their life cycle and ensure their proper disposal (including the recycling of products or product components).

The state should reach out to the venture capital community and engage them in the process of supporting green chemistry in California.

## **STATUTORY AND REGULATORY REQUIREMENTS, ENFORCEMENTS**

The state must develop, implement, and enforce regulations in the public interest without undue influence from parties advancing private interests. It is well established that voluntary measures are insufficient.

### ***Requirements to produce data***

Please see above section on data collection and use information for detailed description of data requirements. The essential principle is that for a chemical to remain on or be placed on the market manufacturers and commercial users of chemicals must provide publicly available information about that chemical. The information must be sufficient to permit a reasonable evaluation of the chemical for human health and the environment.

DTSC should interpret its existing regulatory authority broadly and exercise it. For example, under California Health and Safety Code § 57019, the state has the authority to demand “additional information” from chemical manufacturers using a process of notification. This may be a useful mechanism for requesting data that currently exists on some hazard traits of chemicals or requiring the generation of such data.

Additional legislation to create these data requirements may be necessary.

### ***Program to assess and restrict chemicals***

The state needs to establish a regulatory program to enable it to assess chemicals currently on the market and restrict the use of chemicals based on their hazards. The state must have the authority to restrict, phase out, and ban the use of chemicals that may harm human health or the environment, indicated through the presence of the hazard traits outlined above or by the absence of information about the hazard traits.

As an essential element of such a regulatory program, chemical manufacturers and commercial users of chemicals must be required to demonstrate to the government the reasonable safety of their products in order for those products to remain on or be introduced into the market. Chemicals should not be presumed safe with government bearing the responsibility to demonstrate that a chemical is unsafe in order for it to be regulated. Such a structure undermines producer responsibility, motivates manufacturers and commercial users to resist generating public information about the safety of their products, and makes it unreasonably difficult for government to take steps necessary to protect the public and the environment.

As part of a regulatory program for the assessment of chemicals, manufacturers should be required to demonstrate a reasonable certainty that their chemicals have none of the hazard traits identified above, or any other significant hazard traits that may become known, on the basis of data that is required by the state or that is obtained as a result of a request for additional information by the state or by any other means. Where the state determines that a manufacturer has failed to make this showing, either because of the results of the data or by failing to fulfill the mandatory data requirements, chemicals should not be permitted to remain on or introduced into the market. Thus, the legal standard for whether a chemical is permitted to enter or remain on the market should focus on whether the chemical presents an intrinsic hazard, and not on risk assessment or on balancing safety with economic or other countervailing considerations. Specifically, a structure like that of the Toxic Substances Control Act, which permits use of monetized cost benefit analysis in which economic factors are weighed against human health or the environment, should not be part of any regulatory program under which the state seeks to better manage chemical hazards.

In determining whether manufacturers have demonstrated the safety of their products, the state should ensure that manufacturers:

- 1) Account for the importance of low doses; the significance of background exposures, synergistic effects, and the timing of exposures during the life cycle; and the effects of cumulative exposures and differences in genetic responses to chemical exposure, and
- 2) Evaluate the hazards to the most vulnerable populations, most fragile ecosystems, and most susceptible life stages. Vulnerable populations include pregnant women or women

who may become pregnant, infants and children, people with compromised immune systems, communities that bear an unequal burden of chemical exposure such as workers or those living near polluting facilities or toxic waste sites, and the elderly.

Additionally, the state should ensure that manufacturers consider the different uses of their chemicals and safer alternatives to their chemicals.

There may be circumstances in which chemicals have important uses for which there is currently no safer chemical or non-chemical alternative. The state may want to create provisions for manufacturers to apply for exemptions from chemical use restrictions in such circumstances. In such cases, the burden should be on the manufacturer to demonstrate why a certain use should be exempted, and any exemption should be re-evaluated at least every three years, be structured to minimize exposure to the public and the environment, and be accompanied by a rigorous program to search for safer alternatives.

#### ***Early state action on bad actor chemicals***

The state must take early action on chemicals, including restricting, phasing out, or banning such substances, for which there is evidence of harm or the potential for harm to human health or the environment. These chemicals include carcinogens, mutagens, and reproductive toxicants, chemicals that are persistent, bioaccumulative, and toxic, and chemicals that qualify as very persistent and very bioaccumulative. There are many authoritative bodies that contain lists of chemicals known to the state to have these particular hazard traits, including California's Proposition 65 list, U.S. EPA's lists of carcinogens, the International Agency for Research on Cancer (IARC) list of carcinogens, the National Toxicology Program (NTP) list of carcinogens, mutagens, and reproductive toxicants, and the California Air Resources Board's Toxic Air Contaminants list. The European Union also will be developing a list of chemicals that will be subject to authorization under REACH and should be considered a list developed by an authoritative body.

The state should take action first on those chemicals that are listed on any of the above authoritative body lists and that have been found either in human biospecimens through biomonitoring studies or in environmental media such as air, water, crops, soil, or household dust.

#### ***On-going assessment of chemicals based on data in matrix***

As data about hazard traits and other characteristics of chemicals become available through the matrix, the state should systematically and regularly assess chemicals and make determinations about necessary state actions, including phase out, restriction, or ban, related to these chemicals. The state will have to reevaluate the use of certain chemicals that were previously assumed safe for lack of or inadequate data on health and environmental impacts.

As data become available indicating the presence of hazard traits for chemicals, a process of continually replacing those chemicals with safer alternatives can be a powerful driver for the development of safer alternatives. LEED Certification is an example of a continuous improvement program on which the state can model this particular aspect of its regulatory program. As more information is gathered about the impacts of building materials on the

environment, LEED certification requirements are altered so that the certification criteria are in line with the most up to date science and technology. While the voluntary nature of LEED Certification is not consistent with our overall goals for a regulatory program, its reliance on the “continuous improvement” concept provides useful guidance for the replacement of harmful chemicals with safer alternatives. For chemicals on which the state obtains new hazard trait data, the state should adopt a similar method of institutionalized continuous improvement, applying new knowledge about a chemical or biological reactions to the chemical as part of the chemical assessment.

Over time, as long as the state is moving toward the use of less hazardous chemicals, it will achieve its goals of taking toxics out of products, creating a cradle-to-cradle marketplace, and encouraging a green chemical industry in California.

## **VOLUNTARY MEASURES**

Without a strong and comprehensive regulatory framework (as described in the Data Collection and Statutory and Regulatory Requirements Categories), the Green Chemistry Initiative (GCI) will not achieve the goals the State has put forward. Voluntary programs are not sufficient. There must be a robust framework for regulating chemicals that accompanies incentives for the development of greener chemicals.

The state should provide information and other means to support actions by businesses, agencies, workers and individuals to make choices to use low or no hazard options. Purchasing policies would be an important area to address as an early action measure.

The state should develop policies that avoid the purchase of any hazardous chemicals or products that contain hazardous chemicals and should provide for similar policies for its political subdivisions.

## **EDUCATION AND OUTREACH**

Without a strong and comprehensive regulatory framework (as described in the Data Collection and Statutory and Regulatory Requirements Categories), the GCI will not achieve the goals the State has put forward. Education and Outreach efforts can supplement the framework.

The State of California should ensure that any chemistry curriculum include coursework on toxicology and sustainable design. Toxicology curricula should incorporate the newest science on the effects of chemical exposures, including synergistic, additive, and cumulative exposures, low dose effects, timing of exposure, and differences in genetic responses. Education in this area should not only be for graduate students but should encompass all levels of education, including two-year institutions and undergraduate programs, with increasing complexity and detail in each level. This curriculum should not be treated as an elective but rather as a core component of a chemist’s education. Additionally, this type of curriculum must be a part of a toxicologist’s training.

California is home to world renowned university and research institutions. The state should work closely with these institutions as it develops new testing methods as well as on auditing data that is provided to the state on chemical traits.

The state should provide grants and other support to groups engaged in grassroots outreach, education, and other actions that reduce actual exposure to and risk from chemical use in products or processes.

The state should make information about chemicals to which the public and workers may be exposed more accessible and understandable so as to empower people to avoid hazards. This strategy would include, but not be limited to, mandatory labeling, indicating the presence of chemicals that may be hazardous and the specific hazard trait(s) associated with that chemical.

## **RESEARCH AND TECHNOLOGY**

Without a strong and comprehensive regulatory framework (as described in the Data Collection and Statutory and Regulatory Requirements Categories), the GCI will not achieve the goals the State has put forward.

There may be a place for the state to fund fundamental research on green chemistry, but the majority of development should be undertaken by the private sector. The State of California can create incentives for private research initiatives.

As noted by the National Academy of Sciences in its recent report, current scientific knowledge supports further evolution of testing methods to allow for the detection of early evidence of health effects and to allow for better ways to look at the potential for cumulative effects of mixtures. Considerable expertise on such issues exists in the Office of Environmental Health Hazard Assessment on these needs and issues. CalEPA should be a leader in pushing for the investment in improved testing methods.

## **TECHNICAL ASSISTANCE**

Without a strong and comprehensive regulatory framework (as described in the Data Collection and Statutory and Regulatory Requirements Categories), the GCI will not achieve the goals the state has put forward. In the nature of technical assistance and related to its effort to collect data, the state needs to develop the means to make hazard trait data accessible and understandable for a variety of audiences, including state agencies, businesses, and consumers.

## **RECOGNITION, AWARDS AND CERTIFICATION**

Without a strong and comprehensive regulatory framework (as described in the Data Collection and Statutory and Regulatory Requirements Categories), the GCI will not achieve the laudable goals the state has put forward. The State of California should play a role in creating a sustainable model of production by implementing green purchasing policies that support green businesses and practices.