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The California Safer Consumer Products Program: Evaluating a Novel Chemical Policy Strategy

#### Gina M. Solomon' Anh Hoang' Peggy Reynolds

#### Abstract

In 2008, California enacted laws to restructure chemical policy and promote green chemistry. Ten years after the passage of California's Green Chemistry laws, we assessed their performance through structured interviews with a sample of experts from government, academia, business, and the non-profit sector. We combined the interviews with a scoping literature review to propose a new 10-point framework for evaluating the effectiveness of a chemical regulatory policy, and we assessed the performance of the California law against this framework. The California program performed well on transparency of the regulatory process; protecting vulnerable populations; placing the primary burden on the manufacturer; breadth of regulatory authority, and advancing the public right-to-know. Areas of weakness include, unclear authority to require data on chemical use in products; an inefficient pace of implementation; and limited incentives for innovation. Promoting safer chemicals in products will require additional incentives to protect public health and the environment.

**Keywords:** Chemical policy; Green chemistry; Alternatives analysis; Safer Consumer Products Program; California

#### Background

Most laws designed to protect public health and the environment from pesticides or toxic chemicals are designed around a risk-based framework. <sup>1</sup> Such a framework evaluates each chemical against a standard such as "no unreasonable risk". <sup>2</sup> Under these frameworks, the implementing agency performs a quantitative risk assessment, and then seeks to reduce the risk to levels determined to be acceptable under the statute. <sup>3</sup>

The four steps of risk assessment: Hazard identification, dose-response assessment, exposure assessment, and risk characterization, were first described by the National Research Council (NRC).<sup>4</sup> Quantitative risk assessment in the regulatory context, however, has proven challenging to implement.<sup>5, 6</sup> Data gaps in toxicology, and differences in vulnerability across populations require use of extrapolation and uncertainty factors, decreasing confidence in the resulting numbers. The lack of adequate data on exposure adds additional uncertainty.<sup>7</sup> It is even harder to quantify vulnerability across populations due to factors such as age, co-exposures, co-morbidities, nutrition, genetics, and other stressors.<sup>8</sup> The result is that risk assessments are often debated for years,<sup>6</sup> paralyzing regulatory action on toxic chemicals. More fundamentally, a risk-based framework includes the assumption that reducing the risk below a specified threshold, rather than eliminating the risk by removing the hazard, is the final goal.

In the early 2000's, due to frustration with risk-based chemical regulation, several policy experts proposed a different approach based on hazard identification and alternatives analysis.<sup>9-13</sup> This approach sets as a goal the elimination of the hazard (and associated risk), by replacing toxic chemicals with safer alternatives. Establishment of a hazard removes the need to conduct a full quantitative risk assessment, although some knowledge of exposure remains necessary to prioritize chemicals. The addition of alternatives analysis has the potential advantage of

Solomon G, Hoang A, Reynolds P. The California Safer Consumer Products Program: Evaluating a Novel Chemical Policy Strategy. New Solutions. 1-18, 2019. DOI: 10.1177/1048291119850105. promoting innovation while avoiding substitution of one toxic chemical for another.<sup>10, 14-17</sup> This approach was adopted in several places, including as an element in the Massachusetts Toxic Use Reduction Act;<sup>18</sup> in the authorization component of the European Union Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) regulation;<sup>14, 19</sup> and as the foundation of the California Green Chemistry Initiative.<sup>20</sup> Alternatives analysis has more recently been incorporated into several additional state laws.<sup>21-23</sup>

The 2008 California law created a unique hazard and alternatives analysis framework for regulation of chemicals in products. California's \$2.7 trillion economy is the fifth largest in the world.<sup>24</sup> The state is a major producer, importer, and user of chemicals, with raw chemical sales over \$3 billion annually.<sup>25</sup> For these reasons, California policies regulating chemical safety may have broad impacts.

#### California Green Chemistry and the Safer Consumer Products Program

In 2006, a report by the University of California<sup>12</sup> identified major deficiencies in U.S. regulation of chemicals, demonstrated that those deficiencies adversely affect states including California, pointed to leadership by several major California companies to promote green chemistry, and called for adoption of a comprehensive chemical policy in California that addressed three main deficiencies: The Data Gap, the Safety Gap, and the Technology Gap. The Data Gap referred to insufficient toxicity and exposure information on new and existing chemicals. The Safety Gap referred to gaps in regulatory authority. The Technology Gap related to the need to promote research and development of safer chemicals.

The California Green Chemistry Initiative was signed into law as Assembly Bill (A.B.) 1879 by Governor Schwarzenegger, entering into effect on January 1, 2009. The law required the state to "establish a process by which chemicals of concern in products, and their potential

Solomon G, Hoang A, Reynolds P. The California Safer Consumer Products Program: Evaluating a Novel Chemical Policy Strategy. New Solutions. 1-18, 2019. DOI: 10.1177/1048291119850105. alternatives, are evaluated to determine how best to limit exposure or to reduce the level of hazard posed by a chemical of concern." This law was designed primarily to address the "Safety Gap" identified by the University of California researchers.

A second law, Senate Bill (S.B.) 509, was signed as part of the Green Chemistry Initiative.<sup>26</sup> It attempted to address some aspects of the "Data Gap" by establishing a Toxics Information Clearinghouse for the "collection, maintenance, and distribution of specific chemical hazard trait and environmental and toxicological end-point data." The California Office of Environmental Health Hazard Assessment (OEHHA) was also required to "evaluate and specify the hazard traits and environmental and toxicological end-points and other relevant data that are to be included in the clearinghouse."<sup>27</sup>

The California Department of Toxic Substances Control (DTSC) implements A.B. 1879.<sup>28</sup> The DTSC regulations lay out four steps (Figure 1): Step 1 is creation of a Candidate Chemicals list based on numerous existing authoritative lists; the list currently contains nearly 2,400 individual chemicals and several broad chemical classes.<sup>29-31</sup> The Department then identifies a Priority Product that contains one or more of the chemicals on the Candidate Chemicals list. Once a product is listed, a responsible entity, usually the product manufacturer, must conduct an alternatives analysis (AA) for the product within a specified timeframe. At that point, the Department determines whether to move to a regulatory response. To date the Safer Consumer Products Program has moved very deliberatively, with only three product-chemical combinations finalized and four more in early stages. No products have yet undergone alternatives analysis under this program and no regulatory responses have yet occurred.

<Figure 1 Here>

#### **Objectives**

Ten years after the enactment of the California Green Chemistry Initiative, we evaluated the laws and their implementation to identify strengths of the California chemical policy approach as well as challenges and weaknesses. The evaluation process used expert elicitations supported by a literature review to develop a framework for evaluation of a chemical regulatory system. Interviews with experts from a variety of perspectives then informed an evaluation of the California laws against the framework.

#### Methods

The qualitative study protocol included a scoping review of the literature, interviews with experts in chemical policy representing a range of perspectives, qualitative data analysis of the interview transcripts, and review of draft findings by an Advisory Group and by additional experts who did not participate in the interviews.

#### Scoping Review of the Literature

The goals of the scoping review were to inform and supplement the interviews, and to develop a framework to define the components of an effective model chemical policy. Searches were conducted in PubMed and WestLaw between February and May 2018; with the last searches conducted on 15th May 2018. The full search strategy in PubMed included the medical subject headings (MeSH) terms and text words listed in Table 1.

#### <Insert Table 1 Here>

Exclusion criteria included non-English language publication and publication prior to 2004. After review of the title or abstract, publications were also excluded if they focused only on any of the following categories: drugs, tobacco, firearms, pesticides, hazardous waste, air pollution, ecotoxicity, methods of toxicity testing or risk assessment.

The initial searches generated 517 English language publications. Deduplication and exclusions resulted in seventy four publications that were reviewed in full by one reviewer. Interviewees recommended an additional twenty three publications, resulting in a total of ninety seven publications for review.

Important elements of chemical policy were identified from each publication. Where publications did not include specific recommendations or policies, the publications were categorized as providing general background information. Chemical policy elements were categorized according to topic and used to generate a framework of topic areas for interview questions, and to ultimately focus on a set of ten key elements relevant to chemical policy (Table 2). The purpose of the ten key elements is to provide a framework for evaluating a law and it's implementation, and to apply the framework to the California Green Chemistry Initiative.

## Expert Interviews

The research protocol was reviewed by the Institutional Review Board (IRB) at the Public Health Institute and was determined to be "Not Human Subjects Research" because all participants were interviewed in their professional capacity and no personal information was obtained other than names. All interviewees provided written informed consent and all data were analyzed without personal identifiers.

Potential experts were identified through searches of the published literature, membership on advisory committees, lead commenters on the regulations, and positions as senior government officials. This list was reviewed, refined and expanded by a project Advisory Group of 9 chemical policy experts representing a range of disciplines and perspectives. The resulting list contained 128 potential interviewees.

Interviewees were selected through a purposeful sampling approach. Half of the selected interviewees worked in California, one third worked in other states, federally, and internationally, and the remainder worked both within and outside California. The largest group of interviewees (n=9) worked at state, federal, or international government agencies, with five to seven each from nonprofit organizations, academic institutions, and businesses. Four interviewees worked in multiple sectors. Four experts were interviewed in pairs, resulting in twenty semi-structured digitally recorded interviews with a total of 24 participants in the first round of interviews.

All experts were given the interview questions and consent form in advance. Interviews were conducted in March and April 2018 by one interviewer (GS), in person whenever possible. Interviews were digitally recorded and the duration ranged from 46-102 minutes.

Audio files were professionally transcribed and transcriptions were checked against the audio files by the interviewer. Transcripts were uploaded to Dedoose® for coding.<sup>32</sup> The dual interviews were coded and analyzed as single interviews. Transcripts were read iteratively and coded by two researchers (GS and AH). The coding structure was refined twice after consultation among members of the team, and transcripts were re-coded to the new terms. The data analysis was performed using a combination of qualitative and quantitative content analysis.

Preliminary findings and recommendations were reviewed by all members of the project team and by the Advisory Group. Preliminary findings were also presented to 10 additional chemical policy experts from the initial list, for feedback and additional perspectives and to ensure that no important area was missed.

The performance of the California Green Chemistry Initiative was evaluated against a tenpoint framework that was developed based on the literature review and interviews. The

Solomon G, Hoang A, Reynolds P. The California Safer Consumer Products Program: Evaluating a Novel Chemical Policy Strategy. New Solutions. 1-18, 2019. DOI: 10.1177/1048291119850105. evaluation against each of the ten components was on a qualitative scale to identify strengths and weaknesses (Table 2).

#### Results

#### Strengths of the California Programs

The unique and innovative nature of the law and the California program were cited as strengths in most interviews by experts from all perspectives and sectors (Figure 2). The unique and innovative nature of the program was cited as a strength in 75 percent of the interviews by experts from all perspectives and sectors. Interviewees made statements such as, "I think that California is trying to do things that nobody's done before." [Business scientist]

Experts also emphasized the importance of the program in reformulating consumer products beyond California with comments such as: "If there's going to be some sort of reformulation involved or some sort of labeling involved...they're doing it for all of their products. And so...the scope goes well beyond California." [Business attorney]. Another business scientist added: "I think we'd be kidding ourselves to think that a lot aren't looking at what's in the scope, to think, 'Well, what do we have out there?' So I think that the existence of the program in and of itself has given government a pretty major role in voluntary reformulation."

Other strengths of the program identified by some interviewees included the requirement to conduct alternatives analyses, the large list of chemicals included in the program, the ability of the program to regulate entire chemical classes, and the broad authority that allows the program to address issues missed by other regulations. For example, a scientist who had worked in multiple sectors pointed out that, "[The list] ensure[ed] the department had the ability to grab a class of chemicals. And sometimes a pretty broad class. We'd really like to make sure that people aren't just switching from one chlorinated or brominated flame-retardant to another." Several

Solomon G, Hoang A, Reynolds P. The California Safer Consumer Products Program: Evaluating a Novel Chemical Policy Strategy. New Solutions. 1-18, 2019. DOI: 10.1177/1048291119850105. experts also praised other aspects, including the public process and the focus on protecting vulnerable populations.

Several experts pointed out the importance of the program in promoting innovation and incentivizing safer products. One business scientist said, "[I]n contrast to what people often think, regulation actually causes the creation of jobs, because older technologies tend to be highly optimized and when you obsolete those older technologies or regulate them out, it actually forces companies to do development and actually grows jobs." Several experts indicated that initial regulatory signals are sufficient to drive innovation, but others pointed out that regulations need to be finalized in order to ensure that the entire industry does eventually shift to safer alternatives.

#### <Insert Figure 2 Here>

#### Challenges of the California Programs

Two issues were identified overwhelmingly as challenges: (1) the slow pace of implementation; and (2) limited authority to obtain data on product ingredients and chemical uses in products. Business experts also spoke about challenges associated with confidential business information (CBI) and alternatives analysis. Funding to support the program and to fund green chemistry innovation was also highlighted by numerous experts.

#### Slow Pace

All but one of the experts agreed that the program was moving slowly. There was, however, a lack of consensus as to whether the slow pace was a serious problem. All the experts from the business sector and about half of the government experts pointed to the ambitious breadth of the program and the newness of such a regulatory approach. Many of these experts predicted that the program would speed up naturally with time. For example, one business scientist said, "I don't

Solomon G, Hoang A, Reynolds P. The California Safer Consumer Products Program: Evaluating a Novel Chemical Policy Strategy. New Solutions. 1-18, 2019. DOI: 10.1177/1048291119850105. think it's moving too slowly, I think that it's new and I would rather that we take it fairly deliberately at the beginning to exercise all of these mechanisms that are in place. And each time the department does a task the second or third time, they get better."

Experts from academic and non-profit perspectives, in contrast, generally considered the slowness of the program to be serious and unacceptable. An academic scientist said, "It's just way too slow, it's not going to work." An NGO policy expert commented, "It's just so frustrating that a program that has as much potential around alternatives assessment and regulation has taken so long to do anything." These experts pointed primarily to the cumbersome nature of the procedures in the law and regulations and funding and staffing limitations as the most serious issues that need to be solved. For example, an academic expert said: "The analysis gets to be at an oppressive level that it takes forever to do, instead of noting that the real spirit of the program should be working with firms to get them to identify chemicals to do alternative assessments and move on…" Several also pointed to difficulty obtaining information on product ingredients and the lack of timelines and deadlines during the pre-regulatory period. A few interviewees mentioned that the multiple pre-regulatory public workshops and comment periods add to the transparency of the program but also slow it down (Figure 3).

#### <Insert Figure 3 Here>

Experts from all perspectives pointed to the lack of an expedited pathway through the regulatory process. One NGO expert stated, "there's only one bucket right now under the California program, which may be actually part of its weakness. There is a single approach to every priority product. There's no fast track and there's no R&D track for things that ...[need more development] either." A business scientist commented, "I would think that the process should be agile enough that for something that was egregious the decisions could be made

Solomon G, Hoang A, Reynolds P. The California Safer Consumer Products Program: Evaluating a Novel Chemical Policy Strategy. New Solutions. 1-18, 2019. DOI: 10.1177/1048291119850105. faster." An academic expert agreed, saying: I think where there are clear alternatives and the market is not favoring them in part because of the absence of regulatory pressure so it's totally circular, there should be a very expedited process for DTSC forcing the conventional, more toxic, probably lower cost or otherwise easier product off the market. We should not have a cumbersome process there.

Most experts from the NGO community, academia and government advocated for the legislature to ban hazardous chemicals that are not necessary for the function of a product. As one academic attorney said, "DTSC's process is designed for things where the jury is still out as to what we should do or why we should do it. When it is really a no-brainer and just that you have vested commercial interest in doing it the present way, that's the perfect place for the legislature to step in." In contrast, all of the experts from the business community thought that everything should be addressed through the regulatory process.

#### Data Gaps

The topic of data gaps was the most frequently identified challenge overall. This issue was cited by experts from government, academia and NGOs as one of the principal reasons why the California program has been slow to implement. Interviewees pointed to data gaps in three different areas: chemical use, exposure, and hazard. Most experts believed that the chemical use data gap is a threshold barrier to prioritizing products for potential regulatory action, and therefore the most important to address in the near-term. An academic scientist summarized, "there's so much that's missing on use, application, ingredient information, and it's one of the places [where] there is actually information. It's more about information asymmetry than about actual unknowns." An academic legal expert pointed out that, "[The Department] has to independently figure out that there are one or more chemicals that are worrisome in a particular

Solomon G, Hoang A, Reynolds P. The California Safer Consumer Products Program: Evaluating a Novel Chemical Policy Strategy. New Solutions. 1-18, 2019. DOI: 10.1177/1048291119850105. product before it could engage in various types of data call-in. It couldn't do broad market surveillance and that is very problematic. It is part of the reason this process takes so long." A business interviewee concurred, saying "I don't know whether I would say stumbling in the dark, but it's a fishing expedition...you can spend a lot of time and money looking at things that aren't high-impact."

A few interviewees noted that it can be difficult for companies themselves to obtain information about ingredients from their suppliers, thereby creating challenges for businesses that are seeking to adopt greener chemistries. This has previously been observed by other researchers <sup>33</sup>. One industry chemist noted: "At every step in the supply chain you lose information and you can't retrace it, and that's really problematic. We're so far from tracing back information today. It slows down removing things from products that should have been removed 20 years ago." Recent California legislation requiring disclosure of ingredients in cleaning products was cited by several experts as a potential model <sup>34</sup>. Although there were a variety of perspectives on confidential business information (CBI), a majority of interviewees from all perspectives shared the view stated by one business scientist, "It's valid to move away from the notion that chemical identity could be claimed as CBI and that hazard information can be claimed as CBI. There's a role for formulation information being protected and some process information being protected but we should really be reorienting."

The experts interviewed also noted data gaps in other areas, and predicted that these would be problems in the future. Exposure data gaps were mentioned infrequently, even though potential exposure is an important factor in the prioritization and identification of products. Some experts from NGO, government, and business perspectives did mention the importance of monitoring: "Monitoring is a chronically under-funded environmental area, be that water

Solomon G, Hoang A, Reynolds P. The California Safer Consumer Products Program: Evaluating a Novel Chemical Policy Strategy. New Solutions. 1-18, 2019. DOI: 10.1177/1048291119850105. monitoring, air monitoring, wearable technologies to look at what we are getting exposed to, exposure monitoring. I think that really would accelerate government decision-making." [Government scientist]

Hazard or toxicity data gaps were highlighted as both a challenge and an opportunity. Two areas of need for toxicology data emerged as important: In the future, in alternatives analysis to evaluate data-poor chemicals as possible substitutes; and currently in the identification of emerging chemicals for addition to the Candidate Chemicals List. One business scientist criticized the current Candidate Chemicals list: "What it doesn't do, is it doesn't find things that are new....that list does not cover emerging chemicals. It just doesn't. Everyone knows it doesn't. That's a concern."

Several experts pointed to the chemical hazard traits defined by OEHHA under S.B. 509 in 2011. This aspect of the second of the laws in the Green Chemistry Initiative was variously described as "very powerful", "the foundation to propel us into the next 25 years", "the silent hero", and "brilliant". One scientist who has worked in multiple sectors explained, "It was written in an open-ended way to allow the state to capture toxicological end points - both environmental and human health ones - some of which might not have even really been fully thought about at the time the regulation was written."

Several scientists pointed out the potential link between the S.B. 509 hazard traits and data generated through predictive toxicity testing, such as the U.S. EPA Toxicity ForeCaster (ToxCast<sup>TM</sup>).<sup>35</sup> A government scientist explained, "I see the new scientific information, and methods of read-across, to be melded well with the hazard traits regulation to describe the hazard of chemicals that we don't have a lot of animal data on." An industry scientist agreed, proposing as a prioritization strategy: "...taking thousands of chemicals, some of which have *in vivo* 

Solomon G, Hoang A, Reynolds P. The California Safer Consumer Products Program: Evaluating a Novel Chemical Policy Strategy. New Solutions. 1-18, 2019. DOI: 10.1177/1048291119850105. information, more of which have *in vitro* information on their toxicity and their potency, and then taking a big data approach." This approach to addressing the toxicology data gap was seen as having significant potential, especially for new and emerging chemicals.

#### Need for Green Chemistry Research and Education

Interviewees described the role of government through similar metaphors, including "leveling the playing field", "setting the goal posts", and using "carrots or sticks". For example, an NGO expert stated, "You know, having a carrot is always easier than beating people with a stick. And it's a lot easier to put pressure on somebody to take something bad out if you have something to turn to." Others talked about the role of government in promoting information flow, convening stakeholders, and providing incentives and disincentives.

More than half of the experts, however, felt that government wasn't doing enough to provide strong incentives for green chemistry. A majority of experts from all sectors and perspectives advocated for three things: More interdisciplinary education of chemists; more public-private partnerships to conduct alternatives analysis and to promote green chemistry; and more funding for innovation. A government policy expert stated, "I think the education system has the potential to really change the paradigm." An academic scientist pointed out, "Unlike their support for renewable energy, government isn't...making this a key clean tech issue." An NGO policy expert added, "California could be partnering with billionaires to offer X prizes for the creation of a safer surfactant, or preservative, or something like that." In general, this area was seen as a foundational element for development of safer products that had been left out of the original Green Chemistry Initiative. Most of the experts thought it would be valuable to revisit this issue and advance it as a priority.

#### Chemical Policy Framework

The data from the interviews and the scoping review of the literature were categorized according to key elements of chemical policy, and were distilled down to a framework of ten elements of an effective chemical policy (Table 2). This framework adapts and expands the three gaps identified by Wilson and Schwarzman.<sup>36</sup> Most of the other elements included here have been described elsewhere in different ways and from different perspectives.<sup>37-40</sup>

In our framework, the first two elements map to the Data Gap, and elements 3-9 map to the Safety Gap described by Wilson and Schwarzman <sup>36</sup> (Table 2). Element 10 in our framework maps to the Technology Gap in their framework. The California laws and program include many of the ideal attributes of a successful chemical policy, particularly in the areas of information flow, transparency, and authority to achieve public health protection. The Safer Consumer Products Program also places the burden to evaluate chemical alternatives on the business, and is designed to provide market guidance.

#### <Insert Table 2 Here>

Data and efficiency were two areas that were identified as weak in the California program as described above. Incentives were also identified by most of the experts as an area that has not been adequately addressed. This area is analogous to the Technology Gap in Wilson and Schwarzman (2009). The lack of public funds to support research and development of safer chemicals, and the very few and small university green chemistry programs were identified as continuing barriers to progress.

Although the three major policy gaps identified by Wilson and Schwarzman (2009) remain a very useful framework for envisioning an effective chemicals policy, the framework proposed here contains a more granular set of ten elements that all need to function effectively to regulate toxic chemicals and promote safer chemistry. This framework could be used to evaluate other

Solomon G, Hoang A, Reynolds P. The California Safer Consumer Products Program: Evaluating a Novel Chemical Policy Strategy. New Solutions. 1-18, 2019. DOI: 10.1177/1048291119850105. local, state, national, or international laws and programs, or to compare programs to identify and contrast their strengths.

#### Discussion

The California Green Chemistry Initiative, although functioning well in many respects, is so far not more efficient than more traditional risk-based regulatory strategies. A lack of clear authority to address data gaps related to chemical use and product ingredients appears to be a significant stumbling block. A rigid, cumbersome regulatory process, and limited resources have also slowed the program down. It remains unclear whether a hazard-and-alternatives-based program such as this will show greater efficiency over time if the identified structural challenges are addressed.

Our study was limited by reliance on the opinions of a limited number of experts selected to represent a wide range of perspectives. Interviews with a larger number of experts could reveal additional insights. The iterative nature of the study, involving review of draft findings by a second set of experts and advisors, revealed few new or different insights, suggesting that the selected experts adequately captured the range of views on these topics.

In theory, some of the gaps in California law could be addressed at the federal level. For example, in the 2016 Frank R. Lautenberg Chemical Safety for the 21<sup>st</sup> Century Act <sup>2</sup>. Unfortunately, the reality has not borne out this hope. The Lautenberg Act gives the U.S. EPA the authority to collect exposure and toxicity data on chemicals with issuance of a test order and findings demonstrating that non-animal testing is insufficient if it wishes to require animal testing. In practice, little new information has emerged from the new TSCA authority. EPA does provide multiple useful tools, including non-CBI protected data from TSCA on Chemview,<sup>35</sup> and predictive exposure and toxicology tools on the ToxCast Dashboard.<sup>41</sup> Non-animal testing has

Solomon G, Hoang A, Reynolds P. The California Safer Consumer Products Program: Evaluating a Novel Chemical Policy Strategy. New Solutions. 1-18, 2019. DOI: 10.1177/1048291119850105. progressed significantly, but there are persistent gaps and deficiencies so non-mammalian studies are still insufficient to demonstrate low hazard.<sup>42, 43</sup> The lack of a robust minimum dataset in the new TSCA means that data gaps will continue at the federal level. Provisions to create incentives for green chemistry research and education were removed from the final TSCA reform legislation, apparently due to jurisdictional issues <sup>44</sup>. Separate legislation on this issue introduced in the 115<sup>th</sup> Congress (S. 3296), failed to advance out of committee. As a result, there has been little progress on the federal level to advance green chemistry.

It has become increasingly clear that attempting to solve the Safety Gap identified by Wilson and Schwarzman <sup>36</sup> is unlikely to succeed in isolation. Instead, the full array of gaps must be addressed together to ensure that adequate data are available, information flows through the supply chain and the market, and incentives exist for greener chemistry. With these additional elements, the existing regulatory programs may be able to operate more efficiently and effectively. Specifically, a direct economic driver, such as a fee on toxic chemicals in products, could help address all of these challenges. Such a fee could at once disincentivize the use of toxic chemicals, fund regulatory efforts such as the Safer Consumer Products Program, fund governmental efforts to address the Data Gap (such as by funding governmental exposure monitoring and toxicity screening), and generate a fund that could be used to support Centers for Green Chemistry and technological innovation. With the addition of stronger data collection authority, efficiency measures, and economic incentives, California chemicals policy has the potential to incorporate all the elements of a strong framework for protecting public health and the environment from toxic chemicals.

#### **Statement of Conflicting Interests**

The authors declare they have no actual or potential conflicting financial interests.

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#### References

- Jardine C, Hrudey S, Shortreed J, et al. Risk Management Frameworks for Human Health and Environmental Risks. *Journal of Toxicology and Environmental Health, Part B* 2003; 6: 569-718. DOI: 10.1080/10937400390208608.
- Frank R. Lautenberg Chemical Safety for the 21st Century Act. Frank R. Lautenberg Chemical Safety for the 21st Century Act. 2016.

- Silbergeld EK, Mandrioli D and Cranor CF. Regulating Chemicals: Law, Science, and the Unbearable Burdens of Regulation. *Annual Review of Public Health* 2015; 36: 175-191.
   DOI: 10.1146/annurev-publhealth-031914-122654.
- 4. NRC. Risk Assessment in the Federal Government: Managing the Process. In: National Research Council, (ed.). Washington, DC: National Academies Press (US), 1983.
- NRC. Science and Decisions: Advancing Risk Assessment. Washington, DC: National Academies Press (US), 2009.
- NRC. Review of EPA's Integrated Risk Information System (IRIS) Process. In: Sciences NAo (ed). Washington, DC: National Academies Press (US), 2014.
- NRC. Exposure Science in the 21st Century: A Vision and a Strategy. Washington, DC: National Academies Press (US), 2012.
- McHale CM, Osborne G, Morello-Frosch R, et al. Assessing health risks from multiple environmental stressors: Moving from GxE to IxE. *Mutation research* 2018; 775: 11-20. 2018/03/21. DOI: 10.1016/j.mrrev.2017.11.003.
- O'Brien M. Making Better Environmental Decisions: An Alternative to Risk Assessment. Cambridge, MA: MIT Press, 2000.
- Tickner JA, Schifano JN, Blake A, et al. Advancing safer alternatives through functional substitution. *Environmental science & technology* 2015; 49: 742-749. 2014/12/18. DOI: 10.1021/es503328m.
- Wilson MP, Chia DA and Ehlers BC. Green chemistry in California: a framework for leadership in chemicals policy and innovation. *New solutions : a journal of environmental and occupational health policy : NS* 2006; 16: 365-372. 2007/02/24. DOI: 10.2190/9584-1330-1647-136p.

- 12. Wilson MP, Chia DA and Ehlers BC. Green Chemistry in California: A Framework for Leadership in Chemicals Policy and Innovation. Special Report to the California Senate Environmental Quality Committee and the Assembly Committee on Environmental Safety and Toxic Materials. 2006. Berkeley, CA: California Policy Research Center, UC Office of the President.
- Thorpe B and Rossi M. Require safer substitutes and solutions: making the substitution principle the cornerstone of sustainable chemical policies. *New solutions : a journal of environmental and occupational health policy : NS* 2007; 17: 177-192. 2007/10/26. DOI: 10.2190/NS.17.3.c.
- REACH. Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).
   Regulation (EC) No 1907/2006. 2006.
- 15. Geiser K, Tickner J, Edwards S, et al. The Architecture of Chemical Alternatives Assessment. *Risk Analysis* 2015; 35: 2152-2161. DOI: 10.1111/risa.12507.
- Jacobs MM, Malloy TF, Tickner JA, et al. Alternatives Assessment Frameworks: Research Needs for the Informed Substitution of Hazardous Chemicals. *Environ Health Perspect* 2016; 124: 265-280. 2015/09/05. DOI: 10.1289/ehp.1409581.
- Lavoie ET, Heine LG, Holder H, et al. Chemical alternatives assessment: enabling substitution to safer chemicals. *Environmental science & technology* 2010; 44: 9244-9249.
   2010/11/11. DOI: 10.1021/es1015789.
- Campbell R and Levenstein C. Low-Hanging Fruit: Social Values and Industry Discretion in Toxics Use Reduction Policy. *New Solutions: A Journal Of Environmental And Occupational Health Policy* 2001; 11: 23-39. DOI: 10.2190/xpmj-gx78-aa8r-8ql6.

- Williams ES, Panko J and Paustenbach DJ. The European Union's REACH regulation: a review of its history and requirements. *Critical reviews in toxicology* 2009; 39: 553-575. 2009/08/05. DOI: 10.1080/10408440903036056.
- 20. A.B. 1879. Hazardous materials: toxic substances. *Health and Safety* California2008.
- ME Rev Stat tit. 38 § 1696. Sales prohibition; rules; safer alternatives to priority chemicals.
   2017.
- 22. WA Rev Code § 70.95G.070. Prohibition on the manufacture, sale, or distribution of certain food packaging—Safer alternatives assessment by department of ecology—Publication of findings—Report to legislature—Prohibition effective date contingent on findings. 2018.
- 23. OR 75th Legis. Assemb. S.B. 478. Reg. Sess. Toxic Free Kids Act. 2015.
- 24. Segarra L. California's Economy Is Now Bigger Than All of the U.K, <u>http://fortune.com/2018/05/05/california-fifth-biggest-economy-passes-united-kingdom/</u> (2018, accessed 25 Jul 2018).
- 25. CICC. About. In: Chemical Industry Council of California, (ed.). Brentwood, CA. 2018.
- 26. S.B. 509. Hazardous materials: toxic substances. *Health and Safety* California2008.
- 22 CCR § 69401-69407.2. Green Chemistry Hazard Traits for California's Toxics Information Clearinghouse. 2012.
- 28. Safer Consumer Product Regulations. Safer Consumer Product Regulations. 2013.
- Cowan DM, Kingsbury T, Perez AL, et al. Evaluation of the California Safer Consumer Products Regulation and the impact on consumers and product manufacturers. *Regulatory Toxicology and Pharmacology* 2014; 68: 23-40. DOI: 10.1016/j.yrtph.2013.11.001.
- Krowech G, Hoover S, Plummer L, et al. Identifying Chemical Groups for Biomonitoring. *Environ Health Perspect* 2016; 124: A219-a226. 2016/12/03. DOI: 10.1289/ehp537.

31. CalSAFER. Search DTSC Candidate Chemical Database,

https://calsafer.dtsc.ca.gov/Chemical/search.aspx (2018, accessed 06 Aug 2018).

- SocioCultural Research Consultants L. Dedoose Version, 8.0.42 web application for managing, analyzing, and presenting qualitative and mixed method research data. 8.0.42 ed. Los Angeles, CA: SocioCultural Research Consultants, LLC, 2018.
- Scruggs CE, Ortolano L, Schwarzman MR, et al. The role of chemical policy in improving supply chain knowledge and product safety. *Journal of Environmental Studies and Sciences* 2014; 4: 132-141. journal article. DOI: 10.1007/s13412-013-0158-4.
- 34. S.B. 258. Cleaning Product Right to Know Act. 2017.
- 35. U.S. EPA. ChemView. In: United States Environmental Protection Agency, (ed.). 2018.
- 36. Wilson MP and Schwarzman MR. Toward A New US Chemicals Policy: Rebuilding The Foundation To Advance New Science, Green Chemistry, And Environmental Health. *Environ Health Perspect* 2009; 117: 1202-1209. DOI: 10.1289/ehp.0800404.
- Carroll William F. Upon Further Review: A Commodity Chemist on Green Chemistry. *Physical Sciences Reviews* 2016; 1. DOI: 10.1515/psr-2016-0071.
- Rossi MS, Thorpe B and Peele C. Businesses and Advocacy Groups Create a Road Map for Safer Chemicals: The Bizngo Principles for Chemicals Policy. *NEW SOLUTIONS: A Journal of Environmental and Occupational Health Policy* 2011; 21: 387-402. DOI: 10.2190/NS.21.3.f.
- 39. Green Chemistry Initiative Science Advisory Panel. Green Chemistry Options for the State of California: A Report from the Green Chemistry Initiative Science Advisory Panel to Department of Toxic Substances Control Director Maureen Gorsen. 2008.

- 40. CalEPA. California Green Chemistry Initiative Final Report. In: California Environmental Protection Agency, (ed.). Department of Toxic Substances Control, 2008.
- 41. U.S. EPA. Toxicity Forecaster. 2018.
- 42. Silva M, Pham N, Lewis C, et al. A Comparison of ToxCast Test Results with In Vivo and Other In Vitro Endpoints for Neuro, Endocrine, and Developmental Toxicities: A Case Study Using Endosulfan and Methidathion. *Birth Defects Research Part B: Developmental and Reproductive Toxicology* 2015; 104: 71-89. DOI: 10.1002/bdrb.21140.
- 43. Pham N, Iyer S, Hackett E, et al. Using ToxCast to Explore Chemical Activities and Hazard Traits: A Case Study With Ortho-Phthalates. *Toxicological sciences : an official journal of the Society of Toxicology* 2016; 151: 286-301. 2016/03/13. DOI: 10.1093/toxsci/kfw049.
- Bergeson L. Inside EPA Reports On Loss Of Green Chemistry Provision From TSCA Reform. *Toxic Substances Control Act Blog.* Washington, D.C2016.

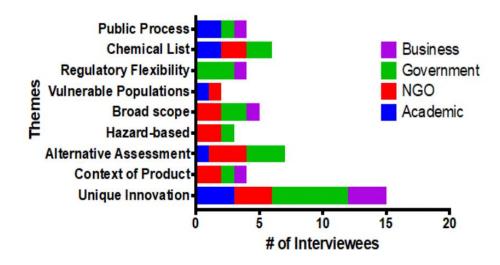
Figure 1: California Safer Consumer Products Program Regulatory Process

# **Safer Consumer Products Framework**

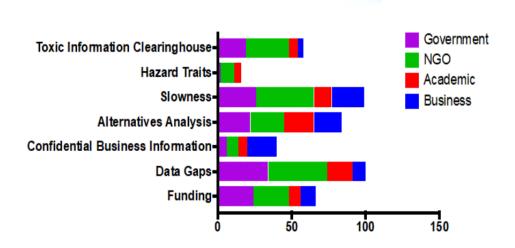


California Code of Regulations, title 22, Chapter 55. Safer Consumer Products. Sections 69501 through 69510. Figure courtesy of DTSC

Figure 2: Strengths of the Green Chemistry Initiative



**Figure 3:** Topics Associated with Challenges to the Green Chemistry Initiative



## Table 1: Search Terms used for Scoping Review

"Confidential business information"[All Fields]

"Safer Consumer Products" [All Fields] AND "California" [All Fields])
"Toxic Information Clearinghouse" [All Fields] AND "California" [All Fields]
"Green chemistry"[All Fields] AND "California"[All Fields]
"Hazardous substances"[MeSH Terms] AND "California"[All Fields]
"Alternatives analysis"[All Fields] OR "Alternatives assessment"[All Fields]
"Chemical policy"[All Fields]
"Chemical safety"[MeSH Terms]

	Essential Element	Examples	Wilson et al. 2009 Concepts	California Activities
1	Data	Obtaining adequate information on product ingredients, exposure, and chemical hazard.	Data Gap	Weak
2	Information Flow	Protecting confidential business information while promoting the public right to know.	Data Gap	Fairly strong
3	Prioritization	Selecting important issues to work on and avoiding less important issues.	Data Gap Safety Gap	Mixed
4	Efficiency	Moving through a process to a conclusion and taking action within a reasonable time period.	Safety Gap	Weak
5	Transparency	Incorporating adequate opportunities for stakeholder input through public workshops, hearings, and written comments.	Safety Gap	Strong
6	Protection	Designing policy actions to protect vulnerable populations, including workers, children, and disadvantaged communities.	Safety Gap	Fairly strong
7	Authority	Ensuring adequate authority to act to protect health and the environment.	Safety Gap	Strong
8	Burden	Placing the burden of demonstrating reasonable safety on the business rather than on the public or the government.	Safety Gap	Fairly strong
9	Market Guidance	Pushing the market toward safer chemicals and avoiding chaotic or perverse incentives.	Safety Gap Technology Gap	Mixed
10	Incentives	Encouraging the growth of green chemistry through public investment in education, research and development.	Technology Gap	Weak

 Table 2: Chemical Policy Framework