VIA ELECTRONIC MAIL

October 11, 2012

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Regulations Section
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RE: Comments on proposed Safer Consumer Product Regulation (R-2011-02) July 27, 2012

Dear Ms. Von Burg:

The American Chemistry Council (ACC)[1] respectfully submits the attached comments and supplemental materials relative to the Department of Toxics Substances Control's (DTSC) proposed Safer Consumer Product Regulation, July 27, 2012 (hereafter referred to as the "proposed regulation").

Our comments highlight our views and questions on issues that we believe require substantial consideration and clarification before the rule is promulgated. ACC has actively and constructively engaged DTSC on the Green Chemistry Initiative for over five years. ACC continues to be an active member of the Green Chemistry Alliance (GCA), and we and our GCA partners have invested considerable effort to provide our best thinking about an approach that meets the requirements of the authorizing statute and fosters a rational, predictable, science-based regulatory environment. We are disappointed that the proposed regulations do not reflect a more objective framework and believe the proposed regulation falls short of achieving the critical tests of clarity, necessity, authority, consistency and nonduplication with California law.

[1] The American Chemistry Council (ACC) represents the leading companies engaged in the business of chemistry. ACC members apply the science of chemistry to make innovative products and services that make people's lives better, healthier and safer. ACC is committed to improved environmental, health and safety performance through Responsible Care®, common sense advocacy designed to address major public policy issues, and health and environmental research and product testing. The business of chemistry is a $720 billion enterprise and a key element of the nation's economy. It is one of the nation's largest exporters, accounting for ten cents out of every dollar in U.S. exports. Chemistry companies are among the largest investors in research and development. Safety and security have always been primary concerns of ACC members, and they have intensified their efforts, working closely with government agencies to improve security and to defend against any threat to the nation's critical infrastructure.

Furthermore, ACC shares the concerns of Senator Michael Rubio regarding the poor economic analysis provided by DTSC. The Economic and Fiscal Impact Statement Form 399, for example, fails to give any indication of potential costs to businesses throughout California, the total number of businesses created, and the number of businesses that will be eliminated. For a regulatory program of this magnitude a better understanding of the economic impact is necessary.

In conclusion, ACC appreciates the degree to which DTSC has engaged all stakeholders throughout the regulation development process. However, we are extremely disappointed that DTSC has ignored many of the substantive comments and suggestions we and our GCA partners have provided. It is imperative that DTSC rectify the issues of clarity, necessity, consistency, authority, and non-duplication, for the regulation will have consequences to businesses and their employees within and well beyond the borders of California.

Sincerely,

Emily V. Tipaldo
Manager, Regulatory and Technical Affairs

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Comments of the American Chemistry Council on the Proposed Safer Consumer Product Regulation (July 27, 2012 (R-2011-02))

October 11, 1012

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Executive Summary

The American Chemistry Council (ACC) appreciates the opportunity to comment on the California Department of Toxic Substances Control's (DTSC) proposed regulations to implement Assembly Bill 1879, as codified in §§25251-25257.1 of the California Health and Safety Code, to promote safer consumer products.

Despite industry's considerable efforts over the last five years to suggest meaningful, practical and legally defensible regulatory alternatives to DTSC, the current proposal demonstrates limited progress in critical areas of the regulation. Although minor changes are reflected, the regulatory Green Chemistry program must have a stronger objective and scientific foundation in order to credibly inform choices made by consumers and other participants in the value chain. In ACC's view, the regulations require considerable additional work before they are made final.

ACC is particularly concerned that the complexity, scope and burden of the proposed regulations will undermine the statutory objectives of minimizing consumer exposure to chemicals that pose risks of harm and promoting innovation. At best the proposed regulation will produce a marginal improvement in human health and environmental safety, but at great expense and lost opportunities for businesses nationwide. Although DTSC has estimated that some 1,200 substances will be covered by the regulation, ACC estimates that the regulation would affect at least 4,000, if not more. Among the significant implementation costs is the need for extensive government resources, at a time when the State is already facing critical resource.[1]

ACC is also concerned that the regulation creates the real prospect of consumer confusion and unwarranted alarm as more than a thousand of the most commercially important substances are designated as subjects of the state's "concern," based only on a loose assessment of hazard characteristics gleaned from lists compiled by other (non-State) entities. In some cases, these lists were developed for purposes far removed from consumer product regulation. In general, the lists are not relevant to the levels of chemical exposure in consumer products. More to the point, consumer apprehension will certainly lead to deselection by the value chain, resulting in product performance which fails to meet consumer expectations and needs. ACC believes that DTSC has not fully assessed the potential for the regulation to result in sports equipment that is less protective, building products that are less weather-resistant or energy efficient, and food packaging that provides shorter shelf life, to name just a few.

Indicative of the ACC's general concern with the proposed regulation is that DTSC's economic analysis fails to provide any meaningful insight into whether the proposal is an efficient and effective means of implementing the relevant Code provisions in the least burdensome manner, as required under California law.

ACC strongly recommends DTSC consider a tailored program that is practical, meets the goals of AB 1879, and is focused on substances in consumer products identified as a potential risk for

[1] The California State Budget 2012-2013 indicates that the State debt is estimated to be $16 billion, coupled with a $3.5 billion tax (revenue) shortfall in the current fiscal year. *See* http://www.ebudget.ca.gov/pdf/Revised/BudgetSummary/FullBudgetSummary.pdf.

human health and the environment based on a scientific assessment of hazard and exposure. We believe that a more direct approach to the implementing regulation would address the practical problems raised by the scope and complexity of the proposed rule. In summary a properly scaled program would:

- Identify a relatively small, initial set of chemical substances that meet specific criteria.
- Identify the consumer product uses of those substances that are not otherwise regulated by federal or state law, or that have exposure and use patterns that may pose risks.
- Prioritize those substances for additional evaluation and review. ACC has developed a chemical prioritization tool that can be adapted to DTSC's use, with appropriate modifications addressing consumer product uses. A copy of the prioritization approach is attached to these comments.
- Identify and prioritize future "batches" of chemical substances using the same approach.
- Request manufacturers and importers of priority products to submit data and information on the chemical substance and its use in the identified consumer product.
- Require alternative assessments only when the chemical of concern in the priority product poses a substantial risk of harm.

Such an approach will allow DTSC to conduct a step-wise, methodical evaluation of chemicals of concern in priority consumer products, provide appropriate notice and information to the public, enhance health and environmental protection, minimize the potential burden to both the State and the regulated community, leverage the considerable work already done by other governments (which is required by statute), and avoid unwarranted negative impacts on the market.

The following areas are of particular concern to ACC and its members. Each area is discussed in Section II in the context of the standards for necessity, authority, clarity, consistency and non-duplication established by the California Office of Administrative Law.

- Identification and Prioritization of Chemicals of Concern
- Priority Product Prioritization Process
- Trade Secrets
- Public Participation and Transparency
- Alternatives Analysis Exemption Threshold

ACC's comments include constructive recommendations for improving the proposed regulation, minimizing its potential negative impacts, and realizing the stated objectives of the underlying statute. We look forward to continuing our work with DTSC toward these mutual goals.

I. General Comments

A. Practicality and Efficient Implementation Should Guide the Regulation

The 78 pages constituting the proposed regulation provide a complex approach to a problem that should be amenable to relatively simple solutions. In an apparent attempt to ensure that the regulation is comprehensive, DTSC has cast a wide net that implicates nearly every segment of the national economy. ACC firmly believes that a more tailored approach is warranted given the concerns raised by the proposed regulation.

ACC supports DTSC's primary objective to protect human health and the environment from harmful exposures to chemical substances. Chemistry touches 96% of all manufactured goods, including the consumer products which are the target of the regulation. The non-confidential federal Toxic Substances Control Act (TSCA) Inventory includes some 85,000 substances (some 7,000 of which are in general U.S. commerce in substantial amounts). Nearly every one of those substances is potentially subject to listing as a "chemical of concern" under this proposed regulation, despite the fact that many are used safely every day, in thousands of applications.

1. Products otherwise regulated by federal law should be excluded.

Until DTSC makes an affirmative determination as to the relationship between the proposed regulation and regulations under other federal or state laws, the regulation applies to products regulated under other comprehensive systems, including the Federal Food, Drug and Cosmetic Act (FFDCA), the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), the Consumer Product Safety Act (CPSA), the Federal Hazardous Substances Act (FHSA), and TSCA.[2] Even food contact packaging – otherwise regulated nationally by the Food and Drug Administration – is subject to the proposed regulation.

The proposed regulation requires an unprecedented level of information about products, chemicals, and manufacturers' business plans and operations to be made publicly available. ACC is particularly concerned that DTSC will not have the staff or financial resources to properly process and manage the volume of information that will be reported under the proposal. Most importantly, DTSC needs to be mindful about how the information related to chemicals used in consumer products is communicated to the public. The proposed regulation will have little value if it simply creates unwarranted consumer anxiety about chemicals (e.g., suggesting a risk of harm where none exists), or imposes regulatory requirements that have marginal impact on health and environmental protection beyond that provided by existing labeling, warning, and use restrictions.

2. DTSC must assure that reliable information is the basis for listing chemicals and products.

The broad scope and complexity of the regulation is exacerbated by an approach that relies on loosely defined "reliable information" as the basis for listing a chemical of concern. It is a general principle of hazard assessment that all available data must be considered and the totality

[2] See attached "List of Federal Statutes Regulating Chemicals".

of relevant and reliable information integrated in order to arrive at a scientifically defensible decision regarding chemical hazard. Since, in many cases, dozens of toxicological studies will be available for review on any given chemical, the only valid scientific approach is to consider the weight-of-the-evidence as part of the standard protocol. A scientifically sound weight of the evidence analysis involves evaluating each study for data quality and reliability and then integrating data from all relevant studies.

Unfortunately, the proposed regulation does not adopt a weight-of-the-evidence approach. Without that approach a single study, regardless of its quality (and irrespective of other available relevant data), could be used to conclude that a chemical possesses "suggestive evidence" of a specific hazard.[3] The framework that DTSC and the Office of Environmental Health Hazard Assessment ("OEHHA") should employ must include a transparent, scientifically-based evaluation of the overall weight of evidence to establish a *causal* relationship between an outcome of concern and exposure to a substance. We urge DTSC to include a weight-of-the-evidence approach in the regulation and articulate it will be used in decision-making, particularly with regard to prioritizing chemicals of concern and products.

3. Aggregate and cumulative risk evaluation imposes considerable burden.

DTSC proposes to consider aggregate and cumulative effects as part of the chemical identification and the priority product prioritization process. It is unclear when, how often and through what process DTSC will evaluate aggregate and cumulative effects. It is also unclear whether this refers to a human health or an environmental assessment of aggregate and cumulative risks, or both. ACC is not convinced that such an analysis is necessary for all chemicals of concern, all priority products or all potential alternatives.

Assessing aggregate effects and risks (the total exposure to a specific chemical from all different sources and routes) requires considerable data and information that manufacturers of individual products typically do not have and may be difficult to readily obtain. Aggregate assessments should only be required on a case-by-case basis for chemicals that meet certain criteria (e.g., cases that present a very narrow margin of safety).

The assessment of cumulative effects or risks (the common toxic effect from concurrent exposure to risks from other chemical and non-chemical sources) poses even greater challenges. Cumulative risk assessment is far from settled science. As with aggregate effects, scientific bodies do not yet agree on an accepted cumulative risk assessment methodology. For example, the most recent cumulative risk assessment recommendations of the U.S. National Research Council expert panel contrast with EPA's current practices and those of the World Health Organization's International Programme on Chemical Safety.[4] In the context of the consumer product regulation, cumulative assessments would quickly become an onerous exercise with little practical meaning.

[3] OEHHA Green Chemistry Hazard Traits for California's Toxics Information Clearinghouse (October 7, 2011), §64206.6(b).

[4] Compare, e.g., Phthalates and Cumulative Risk Assessment: The Task Ahead (2008), Committee on the Health Risks of Phthalates, National Research Council, The National Academies Press, Washington, D.C. with Risk Assessment Of Combined Exposures To Multiple Chemicals: A Who/IPCS Framework (2009). World Health Organization, International Programme on Chemical Safety (IPCS), Harmonization Project DRAFT Document for

It is not clear if DTSC intends to follow the practice of the federal Environmental Protection Agency in assessing the cumulative effects of certain pesticides, which is to conform to the state of the science. The level of knowledge required to conduct a cumulative assessment, even for a group of chemicals that share a common mechanism of toxicity, is orders of magnitude over and above that required to conduct an aggregate assessment, and is not practical for the vast majority of chemical substances, mixtures and uses.

In the 16 years since the federal Food Quality Protection Act (FQPA) was enacted, the science has proven to be so difficult, even for groups of chemicals having a common mechanism of toxicity, that EPA has only been able to conduct cumulative risk assessments for 4 groups of pesticide active ingredients. For all practical purposes, DTSC would require an encyclopedia of all substances arrayed by the adverse effects they are capable of producing and the dose levels associated with such effects, both natural substances and synthetic agents, including consumer products, industrial chemicals and pharmaceuticals and understand the temporal, demographic and geographic exposures to each of these. Beyond that, DTSC would also need to know the background exposure for the chemical being evaluated.

Complicating this analysis is that DTSC would have to go through the same exercise for any additional priority product, add that exposure to the evaluation, resulting in a virtually infinite analysis loop.

Simply, ACC believes there is no practical way to incorporate cumulative assessment as a routine component of the Safer Consumer Product regulation. The burden of analysis on DTSC and the industry would be very high, and will divert scarce resources from managing important risks.

4. DTSC's approach to threshold concentrations is focused on eliminating exposures, rather than minimizing them.

DTSC's proposed regulation and the Initial Statement of Reason (ISOR) indicate that DTSC will defer to the "minimum detectable concentration" level for the "Chemical of Concern" in the product.[5] ACC is concerned that reliance on the limit of detection focuses DTSC's efforts on chemical elimination rather than safe use. This concern is heightened by DTSC's proposed reliance on regulatory responses that provide the greatest level of "inherent protection." .This approach stands in sharp contrast to the statutory requirement that DTSC's regulations must "establish a process for evaluating chemicals of concern in consumer products, and their potential alternatives, to determine ***how best to limit exposure or to reduce the level of hazard posed by a chemical*** of concern, in accordance with the review process specified in Section 25252.5."[6]

Public and Peer Review, available at http://www.who.int/ipcs/methods/harmonization/areas/aggregate/en/index.html.

[5] Initial Statement of Reasons: Safer Consumer Products, R-2011-02, http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/SCP-ISOR-7-23-2012.pdf, p. 104, §69503.5, p. 107, §69503.5(c)(2)(A).

[6] California Health and Safety Code Section 25253 (emphasis added).

A minimum detectable concentration cannot function as an exemption threshold, nor can it be used to document incremental improvement in a particular product. The ISOR importantly notes that "at very low concentrations, it is impossible for analytical instruments to distinguish the difference between signals from analytes and signals created by the instrument."[7] In practical terms, the minimum *detectable* concentration is essentially zero. It is unclear how a manufacturer or importer covered by the regulation would use a minimum detectable concentration to demonstrate reductions in chemicals of concern?

5. DTSC should clarify its authority to impose regulatory restrictions on substances and products.

The proposed regulation also raises an interesting question about DTSC's grant of authority to impose regulatory restrictions. DTSC should address this issue before making the regulation final. The underlying statute permits DTSC to adopt regulations to establish criteria for identifying and prioritizing chemicals of concern and to develop criteria to evaluate them and their alternatives in consumer products (Health and Safety Code §§25252-25253(a)(1)). Additionally, the statute authorizes DTSC to "specify the range of regulatory response that the department may take following the completion of the alternatives analysis" (HSC §25253(b)). ACC encourages DTSC to clarify how the apparent authority to impose product information disclosure requirements, end-of-life management schemes, product bans, and a range of other potential regulatory responses will be exercised.

II. DTSC Should Conduct a More Robust Economic Assessment

DTSC estimates that it will be able to implement the entirety of the program within the Administration's proposed 2012 budget, applying 39 full-time employees and a $6 million budget.[8] ACC believes DTSC has significantly underestimated the costs of the program, and strongly recommends that the Agency conduct a more robust economic assessment of the regulation.

The Chemical Risk Review and Reduction program at the federal EPA has been estimated to cost $40-$45 million (not including new chemicals). Even if California managed to operate at half of EPA's budget, it would still need at least three times more than the $6 million budgeted for the regulation. Based on knowledge of EPA's processes and costs and an independent assessment of the potential costs to DTSC, annual implementation costs are estimated to range from about $9 million to $27.2 million in the first six years, depending on the scope of the Safer Consumer Product program. [9]

California's chemical industry is far more complex than what is depicted in DTSC's economic analysis of the proposed regulation. There are approximately 600 chemicals that are produced in

[7] Id.
[8] Attachment 3 to the Economic and Fiscal Impact Statement (Std. Form 399) Safer Consumer Product Regulations.
[9] For further projected costs to both the state of California as well as the regulated communities, please see the attached reports developed by ICF under contract for ACC: "Potential Costs to the State of California Associated with Implementing the Proposed Safer Consumer Product Alternatives Regulations under CCR 22," July 26, 2012, and, "Addendum: Industry Costs."

the state of California.[10] The value of the chemical shipments is almost $46 billion and the California chemical industry exports $12.5 billion worth of chemicals throughout the world. The business of chemistry directly employs 74,000 people and indirectly contributes 239,000 jobs in California. For every chemistry industry job in California, 4.2 jobs are created downstream within the state. Together these jobs generate $23 billion in earnings which then also generate state and federal revenues through taxes. State and federal income taxes on these industries' payrolls support government programs for the residents of California.

These indicators provide a starting point for a more robust economic analysis of the regulation that assesses the impact of a regulation on the chemical industry and on California's economy as a whole. Dr. Kahn's analysis for the State[11] is not sufficient. The analysis provides no quantitative estimate of costs or benefits, and takes no account of the chemical industry and the downstream impacts in the State.

Similarly, the proposed regulation neglects to mention small businesses or acknowledge potential compliance challenges that small and medium-sized businesses will face as a result of the proposed regulation. While ACC believes that all responsible parties should be held to the same standards, DTSC should consider compliance challenges, particularly costs, for small and medium-sized businesses. We urge DTSC to assess the potential impacts of the regulation on small and medium-sized enterprises.

III. A Review of the Proposed Regulation Against Standards Established by the Office of Administrative Law Establishes a Number of Shortcomings.

A. Necessity (Government Code §11349(a))

1. DTSC should include a weight-of-the-evidence assessment process.

To build overall confidence in the Green Chemistry Program, DTSC must ensure that the regulation adopts a rigorous, science-based approach, in concert with state, federal and international best practices. The reliance on rigorous science must be evident in the selection of chemicals of concern and priority products, in identifying a threshold for and process of alternatives assessment, and in determining what regulatory responses the Agency will take.

The proposed regulations raise significant concerns that the Department will oversee a program that simply accommodates inadequate, unreliable or low quality science. If this occurs, resources will not be directed to the most compelling chemical hazards, but to controversies generated by unreliable studies and amplified by special interest groups and a media that thrives on novel health scares.

Our concerns start with inadequate definitions for "reliable information" and "reliable information demonstrating the occurrence of exposure," which do not require a means to assess

[10] IHS™ Directory of Chemical Producers®, Englewood Colorado.
[11] Attachment 2, "Economic Analysis of California's Green Chemistry Regulations for Safer Consumer Products," Matthew E. Kahn, March 2012.

the quality of information, but focus on whether the information is in the public domain. This problem is exacerbated by an absence of emphasis on a weight of evidence evaluation of information, as well as the dependence on the "most protective" study independent of its actual quality and reliability. Leading to an even more unscientific position is the Department's position that when all other factors are equal, decisions will not necessarily be driven by conclusions from the most relevant and highest quality studies, but rather from the "greater amount of information."

In evaluating information to make decisions and substantiate their conclusions about "the ability of the chemical to contribute to or cause adverse public health and/or environmental impacts," DTSC should be guided by the following principles:

- DTSC's decision-making process must meet benchmarks of objectivity, transparency, and scientific accuracy needed for the public to have sufficient confidence in DTSC's use for health and environmental regulatory decision making. If the process does not meet these benchmarks, there is no assurance that the program will in fact benefit consumers.
- All evaluations must rely on the best available scientific information regarding possible hazards of substances, and must employ consistent, objective methods and models to derive realistic determinations of risks at environmentally relevant levels of exposure.
- Transparent criteria must be established upfront and then consistently applied throughout the evaluation process to identify studies, and to evaluate their quality, relevance, and reliability.
- All evaluations must be based on a framework that takes into account and integrates all relevant studies while <u>giving the greatest weight to information from the most relevant and highest quality studies</u>.
- Hazards and risks must be objectively characterized and presented in a manner understandable to stakeholders and risk managers. Assessments should include central estimates and ranges; it is not sufficient to rely on theoretical maximum exposure estimates to characterize potential risks. The characterization should provide a full picture of what is known and what has been inferred, and should also present results based on alternative plausible assumptions.
- Assessments must provide full disclosure of key information. When assumptions (or policy preferences) are used in lieu of scientific data, the assumptions (and policy preferences) must be disclosed along with the justification for their use. The impact of each assumption on the evaluation should be clearly stated.
- Processes need to be in place to ensure that public comments and peer review findings and recommendations are fully addressed.

ACC believes it is necessary for DTSC to incorporate these principles into Article 1 of the regulations to provide the overall theme and foundation for science-based implementation.

In Sections 69502.2(b)(3) 69503.2(a)(2) of the proposed regulation, it is not clear how or whether a weight-of-the-evidence assessment will be applied when a chemical or a product is being evaluated. It is also not clear whether the Department simply intends to assign a higher priority to the chemical substance that simply has a greater amount of information. DTSC must clarify its approach to weight-of-the-evidence assessments.

2. DTSC must assure it has the resources to manage data and information.

DTSC is proposing to provide an unprecedented (and arguably unnecessary) level of information about products, chemicals, and manufacturer's business plans to the public, public interest groups, competitors, and retailers. Overall, ACC is concerned that DTSC will not have the resources to properly manage the volume of information that will be reported under the existing proposal. DTSC should also be mindful of how the various forms of information are communicated to the public. Specifically, ACC recommends that DTSC exercise a concerted and purposeful communication effort not to create unwarranted consumer or public anxiety regarding the chemicals on the initial list.

ACC encourages DTSC to confer with Washington State and Maine regarding the data collection challenges faced during implementation of the Children's Safe Product Reporting Rule, and the Regulation of Chemical Use in Children's Products, respectively. What will be clear is that to maximize the efficiency and utility of data and its collection, the regulatory need for specific data should be the driver for regulatory requirement for submission, not perceived gaps in the data DTSC possesses.

3. Information certification requirements are not necessary.

ACC is troubled by the proposed requirement to have all information submitted to DTSC signed and certified not only the responsible individual in charge, but also by the owner or an officer of the company, or an authorized representative (§69501.3(a)). While the requirement will certainly draw the attention of upper management, as DTSC no doubt intends, it is also unreasonable and unnecessary. DTSC proposes to review each submission, from Alternatives Analysis Exemption Notifications to Final Alternatives Assessment (AA) Reports. The additional certification requirement is superfluous in the situation where an AA is conducted by a certified assessor, according to DTSC's certification and accreditation process.

4. Key statutory prioritization factors must be included.

As proposed, the regulation identifies a vague, subjective process by which DTSC will prioritize and establish a list of Priority Products. While ACC appreciates that the Priority Products list is apparently intended to be risk-based, as the regulation requires some consideration of exposure and the potential for harm, we also believe DTSC has not adequately represented the three criteria noted in the underlying statute (§69503.2(b)):

1) The volume of the chemical in commerce in this state.
2) The potential for exposure to the chemical in a consumer product.
3) Potential effects on sensitive subpopulations, including infants and children.

DTSC should, at a minimum, include these three items as the "Key Prioritization Criteria."

5. An analytical method for establishment of an alternatives analysis threshold is not needed.

DTSC will require an analytical method for the establishment of each Alternatives Analysis Threshold ("AAT"). §69503.5)(c)(2)(A). It is not clear why the Agency will require this step for substances that already have an established *de minimis* threshold. At a minimum, DTSC should make a clear statement of the value derived from this requirement and the regulatory necessity for the mandate.

6. Additional alternatives assessment exemptions are required.

The proposed regulation indicates where alternatives assessments are not necessary or required. §69505.1(b)(1) – (3). ACC believes the proposed exemptions are consistent with the authorizing statute and recommends that DTSC identify two additional instances where alternatives assessments are unnecessary:

- An alternatives assessment is not required if the responsible entity determines that the Chemical of Concern is not necessary for the product to continue to meet function, performance, technical feasibility, and legal requirements and certifies within 60 days of notifying the Department of its determination, its intent to stop using the Chemical of Concern in the Priority Product and will not use a substitute chemical in place of the Chemical(s) of Concern that is the basis for the priority product designation. The manufacturer must confirm that it has begun the process of removing the Chemical(s) of Concern that is the basis for the priority product determination no later than 120 days after the date the manufacturer notified the Department of its intent; and
- An alternatives analysis is not required if the responsible entity replaces the COC that is the basis for the Priority Product determination with a substitute chemical that is not on the COC list, and thus does not exhibit the toxicity trait(s) that caused the Chemical of Concern to be on the Chemical of Concern List.

7. Sensitive information should not be required in alternatives analysis reports

ACC cautions against requiring information in §69505.5 Alternatives Analysis Reports that unnecessarily results in the submission of large quantities of potentially sensitive personal and business information that is not particularly germane to the core of alternatives assessment reports. For example, the detailed supply chain information required for alternatives assessment should be eliminated, and the detailed facility and location information is not critical to the goals of the program. *See* §69505.5(d).

8. Accreditation bodies and certified assessors are not necessary to achieve the object and purpose of the regulation.

ACC questions the need certification of accreditation bodies and certified assessors. The underlying statute neither explicitly nor implicitly mentions such a regulatory construct. Other chemical management programs across the globe have given rise to a network of sophisticated reputable firms and academic institutions capable of performing such work, thus eliminating the

need for certification and accreditation. The proposed regulation will create a large, bureaucratic process that is not necessary to ensure the conduct of rigorous alternatives assessments or to implement the statute.

9. The selection principles for regulatory responses should weigh multiple factors.

ACC urges DTSC to consider all of the factors outlined in §69506(c)(1-5) when selecting regulatory responses. Selecting a regulatory response is just as much a multi-dimensional process as the evaluation of alternatives. Therefore, it is necessary to weigh efficacy, cost-effectiveness, burden, effects on subpopulations, and enforcement.

B. Authority (Government Code §11349(b))[12]

1. DTSC should clarify its authority to require information generation.

The proposed regulation specifies the ways in which DTSC may collect information "that it determines is necessary" to implement this chapter. In §69501.4(a)(4) DTSC asserts its authority to "request a responsible party or a chemical manufacturer to generate new information and provide it to the Department, in accordance with a schedule specified by the Department." In support of its assertion that it has the sweeping authority to compel the generation of any and all new information "necessary to implement this chapter," DTSC cites to three statutory provisions, none of which in fact support the Department's assertion of such broad authority.

The Department cites to §58012 Health and Safety Code as a basis of its authority to compel the generation of new information. That general grant of authority to "adopt and enforce rules and regulations for the execution of its duties" does not appear to add to the specific grants of authority contained with the Green Chemistry statute (AB 1879), and it is those specific grants of regulatory authority that govern.

The Department additionally cites to Green Chemistry statute §§25252 and 25253 of the Health and Safety Code as authority for its regulation requiring the generation of new information, but

[12] The legislative analysis of the final version of AB 1879 prepared by the Senate Committee on Environmental Quality (August 20, 2008) recognized that a legislative grant of authority to develop a range of regulatory responses that DTSC "may" take does not actually give DTSC a grant of authority to impose the range of requirements on the affected community. The Committee Analysis notes that while the language found in HSC §25253(b) "appears to give the department the authority to take listed actions, this is not explicitly and clearly stated in the bill. Usually, an administrative agency is given authority by the Legislature to take some action and then the authority to adopt regulations to implement the authority" (http://www.leginfo.ca.gov/pub/07-08/bill/asm/ab_1851-1900/ab_1879_cfa_20080821_111017_sen_comm.html). The legislative grant of authority to DTSC to set forth a range of possible regulatory responses it may take gives the Legislature a chance to review those proposed regulatory responses before the Legislature expressly grants DTSC the authority to impose the regulatory responses on the affected community. However, Article 6 of the proposed regulation clearly assumes the presence of express authority that the legislative analysis cited above pointedly notes is missing. We recommend that DTSC obtain an opinion from the Attorney General's office on the scope of the legislative grant of authority to impose the identified regulatory responses, and then provide stakeholders with an understanding of how the Department will exercise its authority in compliance with the Attorney General's opinion.

those specific grants of authority are either silent with respect to, or contradict, the Departments asserted authority in §69501.4(a)(4).

Section 25252 is simply silent on this issue, stating only that DTSC is not limited to adopting regulations that reference and use "available information from other nations, governments and authoritative bodies." That section does not grant the Department the authority to compel a responsible party or chemical manufacturer to generate new information.

Section 25253 is also cited. That section appears to contradict the Department's claim that it may compel entities to generate any and all information that the Department "determines is necessary to implement (the Safer Consumer Products) chapter." Section 25253(b)(2) states only that the regulations adopted by the Department may impose "requirements to provide additional information needed to assess a chemical of concern and its potential alternatives."

There are two key points to be made about §25253. The section merely authorizes regulations that require "additional information," not the generation of new information. The logical reading of the word "additional" in this context is that it means existing information not otherwise available from other nations, governments and authoritative bodies. There is nothing to suggest a grant of authority to require the generation of new testing data or analyses.

Even if one reads "additional" information to mean the generation of new information, which ACC believes is incorrect, it grants authority only to require "information needed to assess a chemical of concern and its potential alternatives." The section is not, under any conceivable reading, a grant of authority to require any and all information that the Department "determines is necessary to implement this chapter," which could include virtually any type of new information.

ACC believes the Department should follow the three-step sequential, tiered process for collecting information set forth in §69501.4(a)(1) – (3). ACC agrees that DTSC should begin its information collection by reviewing information in the public domain that is readily available in a useable format, as laid out in §69501.4(a)(1), followed by reviewing information in the public domain that is available by subscription, and then by requesting additional, existing data from chemical manufacturers or importers. However, as set forth above ACC finds DTSC's requirement to "generate new information"…"necessary to implement this chapter" in §69501.4(a)(4) beyond the scope of the cited authorizing statute.

2. DTSC should not establish the Chemicals of Concern List without public consideration.

ACC questions whether DTSC has the authority to establish a final list of "Chemicals of Concern" without public review and comment. §69502.3. Section 25252 of the Health and Safety Code (AB 1879) stipulates that the regulations are "to establish a process to identify and prioritize chemicals or chemical ingredients in consumer products that may be considered as being a chemical of concern." Stakeholders and interested parties should be afforded the ability to review and comment on the initial Chemicals of Concern (COC) List.

A "list of lists" approach to establish the COC list may be justified by resource constraints, but DTSC must take "ownership" of the resulting list. A California list of COCs, developed by a California process, must also have a California-based process to remove substances from the list.

As proposed, the regulation permits petitions to delist a chemical from the COC list, and DTSC may do so, as long as that chemical is no longer listed on any of the underlying lists (those identified in §69502.2(a)) (emphasis added). Under the proposal, then, delisting is likely to be impossible. Substances would likely remain on the COC list indefinitely – even if they are used safely in consumer products or even if they are not used in consumer products at all. ACC urges DTSC to establish a California list-specific process for delisting chemicals.

3. *Consideration of occupational exposures in the prioritization step should be reconsidered.*

DTSC should reconsider its broad inclusion of workers and worker exposure as part of the product prioritization process. §69503.2. While it is appropriate to consider worker exposure in a retail setting, or perhaps worker exposure to products used in schools or hospitals or other institutional settings, we question whether DTSC has the authority to request information about workers in California or outside the State. At a minimum DTSC should understand how the information requirements may differ from CalOSHA requirements.

4. DTSC's disclosure requirements may put confidential information at risk.

The crux of the proposed regulation is to address "Chemicals of Concern" in specific "Priority Products." §69505.5(j)(2)(C). DTSC's authority to require the disclosure of all known chemical ingredients in the alternative that differ from the original composition will put confidential information regarding new uses of chemicals and new products at risk. Disclosure of the new alternative formulation or composition of the chemicals in the selected alternative is outside of the scope of the regulation, and thus is outside of DTSC's statutory authority to require.

5. Restrictions on trade secret claims threaten innovation.

DTSC's proposed approach to trade secret claims, and to confidential chemical identity in particular, is contrary to the Agency's objective to promote innovation in consumer products and to reduce or replace the presence of substances, in those products, considered to pose a risk of harm. As proposed, the regulation could actually hinder innovation.

In §69510(f) of the proposed regulations, DTSC impermissibly proposes an alteration to California trade secrecy law under the Uniform Trade Secrets Act that is not supported by the implementing statute. Under the proposed regulation, "trade secret protection *may not be claimed* for any health, safety, or environmental information contained in any hazard trait submission *or* any chemical identity information associated with a hazard trait submission." Section 69510(f)(emphasis added). According to the Initial Statement of Reasons, the provision is intended to "effectuate the intent of Health and Safety Code §25257(f), which provides that trade-secret protection may not attach to 'hazardous trait submissions for chemicals and chemical ingredients under this Article [14]'."

Section 25257(f) does not state, however, that "trade-secret protection may not attach" to hazard trait information. It simply notes that "*[T]his section does not apply* to hazardous trait submissions for chemicals and chemical ingredients pursuant to this Article." (emphasis added). The mere fact that §25257 does not apply to hazard trait information does not mean that trade-secret protection may not attach to that information, it simply means hazard trait information is governed by pre-existing law (California Uniform Trade Secrets Act, Cal. Civ. Code §3426 *et seq.)*, rather than the green chemistry statute. By restricting claims for trade secrecy protection for hazard trait submissions, the regulations impermissibly alter the Uniform Trade Secrets Act in excess of DTSC's statutory authority under §25257, and must be revised.

Even if §25257(f) were interpreted to mean that trade secret protection does not attach to hazard trait information, proposed §69510(f) still exceeds the scope of the statute. The proposed regulation does not merely ban trade secrecy protection for hazard trait submission information; it also eliminates trade secret protection for "any chemical identity information associated with a hazard trait submission." However, §25257(f) does state that it does not apply to chemical identity information associated with a submission, just that it does not apply to "hazardous [sic] trait submissions."

The problem with the Department's interpretation of §25257(f) is that it fails to differentiate between "hazard traits," which are specific hazards, such as corrosivity or ignitability, and "chemical identities," which are a separate type of information different than hazard traits. It would it be unreasonable to interpret §25257(f) as preventing persons from claiming trade secret protection for chemical identity information, because chemical identity and formula information is the core of most companies' legitimate trade secrets, as described below. Section 25257(f) speaks to are specific hazards, not chemical identity. A generic name for a specific chemical should be acceptable to DTSC as long as its specific hazard traits are disclosed. Section 69510(f) should be revised to expressly allow companies to claim trade secrecy protection for chemical identity information.[13]

In the chemical industry, trade secret chemical identities are among the most valuable intellectual property. The composition of formulations can be particularly vulnerable, especially for small and medium-sized businesses. The public disclosure of confidential chemical identities would make companies' substantial investments readily available to their competitors, both in and outside the United States.

Health and safety studies and hazard trait information are meaningful to the public without disclosing chemical identities. Structurally-descriptive generic names can provide sufficient information to make studies useful while still protecting trade secret or confidential identities. Generic names allow linkage to the scientific literature on similar chemicals and permit an assessment of the suitability of study methods.

[13] Should DTSC decide to eliminate §69510(f) altogether, subsections (g) and (h) must similarly be eliminated as they have no effect independent of subsection (f).

ACC has tested whether generic names actually lead to relevant health and safety studies. In 2009, the U.S. Environmental Protection Agency changed 530 chemical identities on the TSCA Inventory from confidential to non-confidential.[14] ACC searched the generic and the chemical identity names of a number of these previously confidential substances in Toxline, a common tool to search toxicological literature. What was found should be of interest to DTSC. In many cases, a Toxline search for a generic name for a classified substance identified more studies than did a search for the corresponding CAS number or CAS name.

Other international jurisdictions, such as Canada, have adopted similar solutions, protecting confidential chemical identity in health and safety studies. Australia and Korea also provide protection from disclosure for confidential chemical identities, apparently without regard to whether they are in a health and safety study.

It is critical to California commerce and broader U.S. business interests nationally and internationally that confidential chemical identity is afforded protection as a trade secret. This regulation should not force manufacturers to decide whether to sacrifice their market share in California or their intellectual property, presumably on a global scale.

6. DTSC must prevent the disclosure of supporting information claimed as trade secret.

Under §69510(a), a person "who asserts a claim of trade secret protection" must furnish the department with twelve elements of "supporting information." Assuming that the supporting information would itself contain trade secrets, and not wishing to require the submission of additional information for supporting information claimed as secret, DTSC stated that "if the documentation supporting a claim of trade secret protection contains information that is itself subject to a claim of trade secret protection, such supporting documentation . . . shall not itself require further supporting documentation." DTSC cannot adopt this provision because it conflicts with the California Public Records Act in a manner not supported by §25257 of the Health and Safety Code.

There is a simple solution to this problem. Rather than require entities to submit supporting documentation that is trade secret, DTSC should require that no trade secret information be submitted as supporting documentation under §69510(a). DTSC should be able to make most trade secret determinations without receiving additional trade secret information. If additional trade secret information is not submitted, DTSC will not be obligated to ascertain its validity and protect it against accidental disclosure. Without the added expense of handling unnecessary trade secret information, this approach should reduce costs and lead to more efficient trade secrecy determinations.

In the unlikely event that DTSC is unable to make a trade secrecy determination with the initial round of non-trade secret supporting documentation, DTSC should amend the regulation to allow a specific request for additional information. The regulation should clearly state that the information being acquired is privileged under §1040 of the Evidence Code as "Official Information" because it is being acquired confidentially by DTSC in the course of its public duty

[14] 74 Fed. Reg. 37224 (July 28, 2009).

under the Green Chemistry law and its disclosure is against the public interest because there is a necessity for preserving the confidentiality of the information that outweighs the necessity for disclosure in the interest of justice. So long as DTSC makes clear in the regulation that the additional supporting information is privileged "Official Information," it will be exempt from public disclosure under §§6254(k) and 6255 of the Public Records Act without DTSC having to conduct an additional, costly trade secrecy determination.

ACC also cautions against requirements to submit large quantities of potentially sensitive personal and business information to support alternatives assessment reports. For example, the detailed supply chain information required for alternatives assessment should be eliminated, and the detailed facility and location information is not critical to the goals of the program.

C. Clarity (Government Code §11349(c))

The proposed regulation is rife with uncertainty. The uncertainties, in turn, make implementation and compliance a challenge. This lack of clarity directly contradicts the Office of Administrative Law's standard of clarity, which mandates that regulations be "written or displayed so that the meaning . . . will be easily understood by those persons directly affected by them."[15] Below are examples of this lack of clarity.

1. DTSC should clarify the use of lists developed by other bodies.

Objective chemical selection criteria for the COC list should be used in the regulation, rather than adoption of a "list of lists" developed by other bodies. If DTSC nevertheless decides to adopt a list-based approach as suggested in §69502.2, it is critical that any such lists be developed by authoritative bodies. As proposed, it is unclear what criteria DTSC used to select the underlying lists for COC identification. It is also unclear how DTSC will characterize the chemicals on the COC list. In ACC's view, authoritative bodies include government agencies and formal scientific organizations that:

- Characterize chemicals in an open, deliberative and transparent scientific process in which stakeholders are able to participate formally, communicating directly with the authoritative body through written and oral comments.
- Are widely perceived to be objective, scientifically based, and do not engage in advocacy.
- Base chemical characterizations on a weight-of-the-evidence approach. To the extent available, authoritative bodies consider multiple reliable studies, conducted by different laboratories, at different times, and involving not only different strains but different species and give full consideration to mode of action, confounding factors, maternal toxicity, historical controls and any other scientific information that may be relevant to understanding the potential effects of chemicals on health and the environment.
- Publish their characterizations of chemicals through governmental regulations, periodic reports, monographs or similar publications.

[15] California Government Code, §11349(c).

The confidence of the public and the regulated community in the regulation will be enhanced if DTSC can assure that appropriate processes and the best scientific data available inform the list.

ACC suggests that DTSC list chemicals on the COC list by their individual Chemical Abstract Services numbers (CAS RN). The regulation should specify unique CAS RNs and cannot utilize generic chemical categories. For instance, the perfluorinated chemical category contains hundreds of different unique CAS RN chemicals, each with its own properties. Compliance and the ability to enforce the regulation require clarity regarding the COCs characterization.

Upon the effective date of the proposed regulations, a chemical would qualify as a Chemical of Concern if it (1) exhibits one of 25 environmental or toxicological hazard traits established by OEHHA in its *Toxics Information Clearinghouse* (22 CCR §§69401- 69407.2)*;* and, (2) it appears on one of the lists specified in §69502.2(a) of the proposed rule. Several of the lists are inappropriate indicators of hazard.

1. Category 1 Endocrine Disruptors Identified in the European Commission DG Environment Report. For example, §69502.2(a)(1)(C) references a 2000 report prepared by a consultant for the European Commission entitled *Towards the establishment of a priority list of substances for further evaluation of their role in endocrine disruption*. The preface of the report makes clear that the report was intended as "*a first step towards the establishment, by the Commission, of a priority list of substances for further evaluation of their role in endocrine disruption….*[16]Indeed, the "working list" of 564 chemicals proposed in the 2000 report has been modified substantially over time. 575 chemicals were ultimately screened and evaluated as to their endocrine effects. [17] Of that total:

> 109 substances were not retained in the priority list due to insufficient data on ED effects or insufficient scientific evidence. 147 substances have been excluded from the evaluation during the process as they were identified as double entries, mixtures or of doubtful relevance. [18]

The 2000 report has clearly been superseded by subsequent chemical evaluations, and should not be included as a trigger for hazard classification. For this reason, we urge the Department to delete §69502.2(a)(1)(C) from the proposed rule.

Most importantly, the potential to interact with the endocrine system does not necessarily constitute a health risk. As captured in the widely adopted Weybridge Definition, "[a]n endocrine disrupter is an exogenous substance that causes adverse health effects in an intact organism, or its progeny, secondary (consequent) to changes in endocrine function."[19] The International Programme for Chemical Safety (IPCS – which includes WHO, UNEP and

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[16] BKH Consulting Engineers, in association with TNO Nutrition and Food Research, *Towards the establishment of a priority list of substances for further evaluation of their role in endocrine disruption*, November 10, 2000.
[17] European Commission, *Endocrine Disruptors Website*, http://ec.europa.eu/environment/endocrine/documents/sec_2007_1635_en.htm.
[18] European Commission, *Endocrine Disruptors Website*, http://ec.europa.eu/environment/endocrine/documents/sec_2007_1635_en.htm.

[19] European Workshop on the Impact of Endocrine Disruptor on Human Health and Wildlife (Weybridge UK; 1996). European Union Report EUR17459.

ILO), utilizes a similar definition, "[a]n endocrine disrupter is an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effect in an intact organism, or its progeny, or (sub)populations."[20]

Endocrine-mediated effects have already been captured by other lists, selected by DTSC that include reproductive, developmental and other adverse outcomes.

2. Group 2B carcinogens identified by the International Agency for Research on Cancer (IARC). The IARC Group 2B list is composed of substances for which there is limited human evidence and insufficient animal evidence of carcinogenicity.[21] It is possible that chemicals classified as IARC 2B will have some evidence or carcinogenicity based on animal models, but stronger evidence against carcinogenicity from available human epidemiology studies. ACC strongly suggests that the IARC 2B characterization be removed from §69502.2(a)(1)(I).

Under IARC guidance, there are a number of issues when evaluating chemicals with "limited evidence of carcinogenicity," and therefore a definitive evaluation of cancer hazards cannot be made. For example, a definitive evaluation may be difficult due to the following: the evidence of carcinogenicity is restricted to a single experiment; there are unresolved questions regarding the adequacy of the design, conduct or interpretation of the studies; the agent increases the incidence only of benign neoplasms or lesions of uncertain neoplastic potential; or, the evidence of carcinogenicity is restricted to studies that demonstrate only promoting activity in a narrow range of tissues or organs.[22]

3. National Toxicology Program, Office of Health Assessment and Translation Reproductive or Developmental Toxicant. Another list that is inappropriate for purposes of qualifying COCs is proposed in §69502.2(a)(1)(L). That provision refers to "reproductive or developmental toxicants identified" in monographs produced by the National Toxicology Program, Office of Health Assessment and Translation (OHAT). OHAT is the successor to the Center for the Evaluation of Risks to Human Reproduction (CERHR).

A brief background on how CERHR/ OHAT monographs are structured demonstrates why §69502.2(a)(1)(L) is an inappropriate factor in designating Chemicals of Concern under the California Green Chemistry Program. CERHR/OHAT monographs classify chemicals based on:

> (1) the weight of scientific evidence on adverse effects, expressed on a seven-part scale ranging from "clear evidence of adverse effects" to "clear evidence of no adverse effects"; and

[20] World Health Organization International Program on Chemical Safety, "Global Assessment of the State-of-the-Science of Endocrine Disruptors," WHO/PCS/EDC/02.2, Chapter 1: Executive Summary.
[21] World Health Organization International Agency for Research on Cancer Monographs on the Evaluation of Carcinogenic Risks to Humans, Preamble, p. 23 (http://monographs.iarc.fr/ENG/Preamble/CurrentPreamble.pdf).
[22] World Health Organization International Agency for Research on Cancer Monographs on the Evaluation of Carcinogenic Risks to Humans, Preamble to the IARC Monographs, B. Scientific Review and Evaluation, 6. Evaluation and rationale (b) Carcinogenicity in experimental animals (http://monographs.iarc.fr/ENG/Preamble/currentb6evalrationale0706.php).

(2) the agency's level of concern that a chemical is associated with various reproductive and developmental effects, expressed on a five-part scale ranging from "serious concern for adverse effects" to "negligible concern for adverse effects.

In the second analysis, the agency may also find that "insufficient hazard and/or exposure data" exists.

A CERHR monograph can therefore determine that a particular chemical presents "clear evidence of no adverse effects" and express "negligible concern for adverse effects." Nevertheless, under a plausible interpretation of §69502.2(a)(1)(L), that chemical could be qualified as a Chemical of Concern because it was "identified" in a CERHR/OHAT monograph. We respectfully recommend that §69502.2(a)(1)(L) be eliminated from the proposed rule, or alternatively, that DTSC make clear that *only CERHR/OHAT monographs indicating high levels of evidence and concern* regarding reproductive and developmental effects be considered as the basis for addition to the COC list.

2. DTSC should make clear how it will use the key criteria to identify priority products.

As proposed, it is unclear how DTSC will objectively utilize the "Key Criteria" to assess and prioritize products based on a list of over twelve hundred potential chemicals of concern. §69502.3(b). An objective, step-by-step process should be constructed, based on credible, scientifically valid criteria that clearly outline the process by which DTSC will identify priority products. The use of a highly subjective process based on a narrative standard is not acceptable from a scientific or public policy standpoint, as it leaves the door open for political decision-making.

The incorporation of "the ability of the Chemical of Concern in a product *to contribute to or cause* adverse public health and/or environmental impacts," (emphasis added) as criteria for prioritization is unclear. This phrasing is contrary to a risk-based approach in the implementation phase of prioritization and strays from the statutory use of the term "potential to cause." ACC suggests DTSC revise this phrase to read, "The *potential* for the Chemical(s) of Concern in a product *to cause* adverse public health and/or environmental impacts…".

The proposed "narrative standard" for the prioritization process (§69503.3 of the proposed rule) also creates significant uncertainties. Although DTSC has indicated its goal is to prioritize a small number of products for review, the proposed rule does not articulate a clear, step-by-step process for doing so. The proposal indicates that DTSC may rely on information developed or received under the regulation, but is not limited to such information in reaching a prioritization decision. The lack of explicit description raises questions about the nature and type of information DTSC, in fact, might use to reach a decision.

The proposed regulation lays out multiple criteria to be used in prioritizing products for review, with products meeting "one or more" of the key criteria to be considered priorities. The

regulation should be clarified to focus, at least in the first few years of the program, on products that meet all three statutory criteria (as high priorities).[23]

From the proposal, it appears that the key prioritization criteria are secondary to the longer list of other criteria that precedes the "Key Criteria" (§69503.2). DTSC should clarify the relationship between the key criteria and what is better characterized as supporting evidence.

Other information DTSC proposes to use, however, is too ambiguous and may not be appropriate as part of this exercise, or may be claimed as confidential information. The proposed rule states, "[t]he Department shall consider the potential adverse public health and environmental impacts…" associated with a number of hazard and exposure scenarios. This information may be extremely diffuse, poorly defined or difficult to obtain, reliably, for the department to consider.

For example, the proposal specifies that DTSC shall give special consideration to the type and severity of potential adverse impact(s), and the potency of the chemical(s) associated with the adverse impact(s), for children, pregnant women, and other sensitive subpopulations. ACC agrees that certain demographics, primarily children, should be given distinct consideration. However, the term "sensitive subpopulations" as defined by DTSC in the proposed regulation is a vague and highly subjective term ("including but not limited to" §69501.2(a)(72)) that may include different demographics or conditions depending on the context. See "sensitive subpopulations" under Clarity, Definitions above.

In many cases it will be difficult to obtain product exposure information relating to "manufacturing, use, storage, transportation, and end-of-life management practices and the locations of these practices." The proposed regulation seems to expect consumer product manufacturers to have comprehensive manufacturing, use, distribution, and disposal data for every unit of its product. This is not a practical expectation. It becomes increasingly difficult to monitor the exact movement of products once they are sold to distributors and to primary and secondary retailers.

Similarly, with the exception of a few product categories, most consumer products find their way to a landfill or recycle stream at the end of their useful life, although it is often difficult to track the exact path of the product. As DTSC is surely aware, end of life management practices are commonly predisposed by municipalities in which the products reach the end of their useful lives, rather than by manufacturer or retailer plans. A manufacturer would clearly not know that location at the time of production or sale. The regulation should hold regulated entities accountable only for information that it can be reasonably expected to obtain.

The proposed rule indicates DTSC will consider the availability of reliable information to substantiate potential adverse impacts and exposures in the prioritization process. ACC believes that DTSC should also consider reliable evidence that refutes potential adverse impacts or exposures.

[23] Three statutory criteria: 1) The volume of the chemical in commerce in this state; 2) The potential for exposure to the chemical in a consumer product; and, 3) Potential effects on sensitive subpopulations, including infants and children.

3. DTSC should clarify the process for evaluation of aggregate and cumulative effects.

The proposed rule fails to mention what framework DTSC will use, as well as what framework(s) responsible entities may use, during the alternatives assessment process to evaluate aggregate and cumulative risk. §69503.2(a)(1)(A)1.b./c.[24] ACC urges DTSC to specify what process will be used to determine when an aggregate and cumulative risk assessment is necessary, and, what framework will be used to do so. Specifically, DTSC should clarify whether it is referring to both an assessment of human health aggregate and cumulative risks, and, environmental aggregate and cumulative risks.

It is impractical to require an assessment of aggregate and cumulative risk for all chemicals of concern or all priority products. Assessing aggregate risks from the total exposure to a specific chemical from all different sources and routes requires considerable data, about each and every use of a substance, information that manufacturers of individual products do not have and cannot readily obtain. Aggregate assessments should only be required for those chemicals that meet specific criteria, such as cases that present a very narrow margin of exposure.

The assessment of cumulative risk – the evaluation of a common toxic effect from a concurrent exposure to a group of chemical and non-chemical risks that act in the same way poses even greater challenges. Similar to aggregate risk assessment, cumulative risk assessment is far from settled science. Scientific bodies do not yet agree on an accepted cumulative risk assessment methodology. Cumulative risk assessment may require manufacturers to look at all the adverse effects caused by the chemical in question, and to evaluate all other chemicals that potentially cause the same adverse effects (not just those in humans, but also in animal studies where doses are typically hundreds, thousands or even tens of thousands of times higher than humans ever experience). In the context of consumer product regulation, cumulative assessments would quickly become an onerous exercise with little practical meaning.

ACC urges DTSC to adopt the best available framework regarding combined exposure to multiple chemicals, developed and endorsed by the World Health Organization (WHO)/ International Program on Chemical Safety (IPCS) (see attached). The framework is designed to aid risk assessors in identifying priorities for risk management for a wide range of applications where co-exposures to multiple chemicals are expected; and, it builds on previously published guidance for priority setting and assessment of combined exposures.[25] A framework assessment would provide DTSC with a problem formulation process for each combined exposure situation. Roughly, DTSC would begin by asking a series of questions to formulate the problem, and then for example, the initial Tier 1 assessment would begin with the upper-bound levels of daily intake for the majority of the identified population (exposure), and, potency for the most sensitive endpoint (hazard). Based on necessity, DTSC may then revise the exposure and hazard assumptions, replacing with increasingly detailed data and models.

[24] The proposed regulation refers to "aggregate effects" and "cumulative effects," whereas typically these are referred to as "aggregate risk" and "cumulative risk."

[25] M.E. (Bette) Meek, Alan R. Boobis, Kevin M. Crofton, et al, "Risk assessment of combined exposure to multiple chemicals: A WHO/IPCS framework," Regulatory Toxicology and Pharmacology, v 60 (2011) S1-S14, p 51.

4. Minimum Detectable Concentrations should not be the alternative analysis threshold.

Language in the ISOR suggests that the default Alternatives Analysis Threshold (AAT) will be the minimum detectable concentration for intentionally added chemicals:

> **Section 69503.5**, in its entirety, provides an exemption from the requirement of conducting an alternatives analysis for a Priority Product when specified criteria are met. The distinction between those Priority Products that are subject to the alternatives analysis and those that are exempt will be primarily based on the minimum detectable concentration for the Chemical of Concern and the difficulty of avoiding the presence of contaminants that are the source of the Chemical of Concern.

Functionally speaking, the detectable concentration or limit of detection is the lowest possible level of the chemical in the product. Beyond the limit of quantitation, detection may only be a binary (present/not present) outcome, rather than a quantitative amount. If this is the case, DTSC has not been clear about how the AAT will be used to demonstrate reductions of COC in the Priority Products. AB 1879 establishes that both limiting exposure to the COC(s) or reducing the level of hazard posed by a COC are goals of the regulation.[26] What is less apparent, however, is how a responsible entity will be able to demonstrably reduce the level of a COC in the Priority Product below the limit of detection. ACC asks that DTSC clarify whether the limit of detection will be the preferred AAT.

Satisfying DTSC's AAT exemption requirements will be a significant analytical burden for product manufacturers. At a minimum considerable product testing will be necessary to substantiate the exemption, and that the AAT will likely be at the level of detection. Most industrial chemicals are not pure; in essence many are mixtures.

As proposed, the regulation does not distinguish between intentionally-added constituents and contaminants, and every product might have a trace amount of a COC and would require analysis. Furthermore, responsible entities cannot control the state or pace of analytical chemistry. Establishing the limit of detection as a regulatory threshold effectively sets a moving target. The degree to which small and medium sized businesses, much less importers and retailers, would have access to and resources to put toward this level of analytical chemistry is questionable and impractical.

Furthermore, the proposed AAT threshold and the process for establishing the AAT are not consistent with the processes used by federal and international agencies. ACC strongly recommends that DTSC set numerical thresholds that are harmonized with those applied by federal and international agencies. This would be consistent with the enacting statute that specifies

> [T]he department shall reference and use, to the maximum extent feasible, available information from other nations, governments, and authoritative bodies that have

[26] Assembly Bill 1879, Section 1.

undertaken similar chemical prioritization processes, so as to leverage the work and costs already incurred by those entities and to minimize costs and maximize benefits for the state's economy.

The federal Occupational Safety and Health Administration (OSHA), the Globally Harmonized System for Classification and Labeling (GHS), and the European Union's REACH standard apply a *de minimis* threshold of 1% for hazardous chemicals, and 0.1% for carcinogens, mutagens and reproductive toxins. Further, ACC urges DTSC to distinguish between intentionally-added chemical ingredients and contaminants, and subject contaminants to a higher threshold.

The AA process also warrants other clarifications. Section 69505.4(a) does not make clear what criteria will be used to judge when an when an alternative makes a "demonstrable contribution" to one or more adverse public health, environmental, waste and end-of-life, and/or materials and resource consumption impacts of the Priority Product. Section 69505.5(d)(5) fails to articulate what bearing the proximity of the place of product manufacture to virgin or recycled resources has on a DTSC decision. At a minimum, this information could very well be commercially sensitive, pertaining to the costs of doing business, and it will likely be claimed as trade secret.

5. Many definitions should be clarified.

- "Adverse air quality impacts" (§69501.1(a)(3)). It is unclear what is meant by "air emissions of any of the air contaminants . . . *that have the ability* to result in adverse public health, ecological, soil, or water impacts," (emphasis added). It is not clear what this means in practice. For example, it is not clear what DTSC intends by referencing air contaminants with an "ability" to produce adverse impacts. "Alternative" (§69501.1(a)(11)(C)). The meaning of "redesign of a Priority Product and/or manufacturing process, *using different materials* to reduce or restrict exposures to Chemicals of Concern in the Priority Product," (emphasis added) is not clear. DTSC should consider eliminating the phrase "using different materials." "Hazard trait submission" (§69501.1(a)(33)). The proposed regulation states that "[W]hen any study or datum indicates that a chemical manifests any hazard trait, chemical identity is part of any hazard trait submission." According to OEHHA's Green Chemistry Hazard Trait Characteristics, every chemical will manifest some hazard trait. This provision, therefore, is meaningless.
- "Homogeneous material" (§69501.1(a)(34)).DTSC proposes to identify and prioritize specific materials, regulating specific uses of a material. The definition of "homogenous material" is taken directly from the European Union's Restriction of Hazardous Substances Directive (RoHS). "Homogeneous material" is not well-defined, however, as it may be "one material of uniform composition" or "a material, consisting of a combination of materials." Attempting to harmonize with a problematic term will make compliance difficult for both DTSC and responsible entities.

  ACC suggests that DTSC remove the term from the regulation and make a consequent revision in the definitions of "component," as well as "consumer product" or "product" as suggested below:

(21) "Component" means a uniquely identifiable part, piece, assembly, subassembly, or a material within a part, piece, assembly, subassembly, of a consumer product that:

(A) Is required to complete or finish an item

(B) Performs a distinctive or necessary function in the operation of a product or part of a product

(C) Is intended to be included as a part of a finished item

(22)(A) "Consumer product" or "Product" means any of the following:

1. A "consumer product" as defined in Health and Safety Code §25251;

2. A component, or uniquely identifiable material within a component, that is identified under §69503.4(a)(2)(B), as the minimum required focus of an AA.

- "Reliable information" (§69501.1(a)(52)). The definition of "reliable information" lacks rigor and lacks a weight-of-the-evidence evaluation. However, the ISOR discussion of "reliable information" includes a number of internationally-accepted testing guidelines and protocols. It is not clear why these guidelines and protocols not been included in the regulatory language. [27] ACC urges DTSC to include these guidelines, practices and protocols in the regulation, and to specifically note:
- Whether the study has been replicated;
- Whether the study provided was conducted according to generally accepted principles, including test protocols:
    - US FDA Good Laboratory Practices (Part 58 of Title 21 of the Code of Federal Regulations)
    - US EPA's Office of Chemical Safety and Pollution Prevention Harmonized Test Guidelines
    - TSCA (Chapter 1 of Title 40 of the Code of Federal Regulations)
    - TSCA Testing Guidelines (Parts 798 and 799 of Title 40 of the Code of Federal Regulations)
    - OECD Guidelines for Testing of Chemicals
    - OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring
    - OECD Manual for Investigation of High Production Volume Chemicals
    - REACH/ECHA Guidance on Information Requirements and Chemical Safety Assessment and Regulation (EC) No. 440/2008 of the European Parliament and the Council
    - CEPA Guidelines for the Notification and Testing of New Substances: Chemicals and Polymers.

- "Responsible Entity" (§69501.1)(a)(54)). For clarity and consistency with other existing regulations ACC suggests that DTSC adopt a definition of "manufacturer" that is consistent with the Fair Packaging and Labeling Act (FPLA; 15 U.S.C. §§1451-1461).

[27] *See*, however, Initial Statement of Reasons: Safer Consumer Products, R-2011-02, http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/SCP-ISOR-7-23-2012.pdf, p. 33-34.

For products manufactured in a foreign country and imported into the U.S., FPLA requires that the entity that receives the product shipment in the U.S. must assure that the product carries U.S.-compliant labeling that identifies the entity for which the product is "manufactured for" or "distributed by." It is practical for DTSC to start with the entity identified on the product label pursuant to FPLA requirements as an initial point of contact for imported products rather than assign the duty to comply to a foreign manufacturer or retailer.

- "Sensitive subpopulations" (§69501.1)(a)(58)). It is not clear what DTSC means by sensitive subpopulations representing "a meaningful portion of the general population?" The definition of "sensitive subpopulations" is too broad and may present significant issues of compliance for responsible entities depending on how this term is interpreted. There is likely broad agreement that infants, children, pregnant women, elderly individuals, and individuals with a history of serious illness should be included within the definition. However, the use of the phrase "including, but not limited to…" inappropriately confers upon the Department unlimited and arbitrary discretion to define the universe of "sensitive subpopulations" in ways that the regulated community cannot anticipate. DTSC should carefully review the proposed regulation for such instances of open-ended language such as the definition of "sensitive subpopulations" in this and other sections, giving careful consideration to the inability of product manufacturers, importers, and retailers to comply with such vague regulatory language that could give rise to shifting interpretation over time.

  It is similarly not clear why the proposed regulation include workers and their occupational exposures as a "sensitive subpopulation?"
- "Technically and economically feasible" (§69501.1)(a)(59)). It is not clear what DTSC means when it indicates that "[t]he technical knowledge, equipment, materials, and other resources available in the marketplace *are expected to be sufficient* to develop and implement the alternative, and to meet consumer demand after an appropriate phase-in period," (emphasis added). ACC believes a better articulation would be that the information "are sufficient." ACC supports DTSC's incorporation of consumer acceptance as part of the overall feasibility of a potential alternative.

6. The bulk chemical exemption should be restored.

The goal of the California Green Chemistry Initiative is to provide better, safer options to California consumers, in terms of the products they use on a daily basis. The focus of the "Safer Consumer Product Regulation" is the "Chemical(s) of Concern" in a particular "Priority Product." Therefore, ACC is unclear why DTSC has included bulk chemicals within the scope of a "consumer product." Federal agencies and federal statutes regulate chemicals and materials; and federal statutes and agencies, such as the Occupational Safety and Health Administration (OSHA) regulate the manufacturing workplace, as well as the Division of Occupational Safety and Health (Cal/OSHA), within California. Furthermore, the Department of Transportation and Department of Homeland Security also regulate the movement and transport of chemical goods.[28] ACC recommends that the exemption be restored.

[28] See attached list of federal statutes that currently regulate chemicals in U.S. commerce.

7. DTSC should clarify certain information submission and retention requirements.

The purpose of §69501.3(d) is unclear, and DTSC should clarify its intention. The provision states:

> A person who is subject to a requirement to obtain or prepare information, but who is not required to submit the information to the Department or has not yet been requested to submit information to the Department, shall retain the information for a period of three (3) years following the date the person was required to obtain or prepare the information.

A literal reading of the provision would require persons not subject to the regulation (those not required to submit information) to retain information for up to three years. All required information will be submitted to DTSC in some format. ACC requests that DTSC provide an example of the type of information referenced in the provision and the type of person expected to be affected.

Similarly, Section 69501.4(a)(1-4) also fails to make clear who may be responsible for information submissions in the future. In addition, §69501.4(d) does not make clear what information DTSC would consider "helpful" to the Department. ACC suggests using the term "reliable information" in this instance.

8. Additional clarity on the standard for demonstrating an inability to respond should be provided.

The last provision of §69501.5(c) describes the process by which the responsible entity, chemical manufacturer or importer may find itself on the Response Status List. The responsible party in this case must demonstrate to DTSC's "satisfaction that it does not have and is unable to produce the requested information" or, DTSC may post the responsible party's identifying information on DTSC's web site. However, it is unclear how a responsible entity, chemical manufacturer or importer may demonstrate to the Department's satisfaction that it <u>is not</u> able to produce the requested information. For example, DTSC might better articulate the objective standard of proof for such demonstrations.

9. *DTSC should address its intention to respond to public comments.*

Transparency in DTSC's processes is crucial, and therefore, DTSC should clarify the role of the Department in responding to public comments. See, e.g., §69502.3(d). The success of DTSC's regulation depends in large part on the degree to which the compliance and decision making processes are transparent. It is good practice to require DTSC to respond to any and all substantive public comments, but the proposal lacks this basic process protection. For example, the COC listing process allows DTSC the discretion to respond to "some or all" public comments received on revisions to the list. Regulated entities materially affected by DTSC's decisions, and the public, should be able to understand the basis for the decisions, and DTSC's

reasoning in accepting or rejecting particular recommendations, data, and/or information. ACC strongly recommends that DTSC's default approach be to respond to all public comments.

10. DTSC's requirement to apply for an exemption from the response requirement places a significant burden on the regulated community, and appears inconsistent with the statute.

Section 69506.11 is intended to implement the provision in §25257.1 of the statute. Subdivision (b) of the statute provides that, "This article does not authorize the Department to supersede the regulatory authority of any other department or agency." Subdivision (c) provides requires the Department to reform from duplicating or adopting conflicting regulations for product categories already regulated or subject to pending regulation.

Section 69506.11 of the regulation puts the burden on the responsible entity to apply to the Department for an exemption. The exemptions are to be based on a conflict of one or more requirements of another California or federal regulatory program. The second basis for an exemption is that the proposed regulatory response "substantially duplicates" one or more requirements of another California or federal regulatory program, "without conferring additional public health or environmental protection benefits." ACC requests that the Department clarify this section based on the following three points:

- Nothing in the statute imposes the burden on the responsible entity to apply for an exemption. The Legislature imposed the responsibility on the DTSC to implement that provision. It does not contemplate imposing the burden on responsible entities.
- With respect to paragraph (6)(B) of subdivision (a), limiting the exemption of substantially duplicating one or more requirements of another regulatory program to circumstances where the proposed regulatory response does not confer additional public health or environmental protection benefits. This provision exceeds the Department's authority. Nothing in the section contemplates that DTSC or the Department may duplicate other regulatory programs solely on the Department's contention that greater public health or environmental protection will result.
- The Department has ignored the fact that subdivision (b) of §25257.1 prohibits the Department from superseding the regulatory authority of any other department or agency. By imposing a program, even if it provides additional public health or environmental protection, may well supersede the other agency's regulatory program.

D. Consistency (Government Code §11349(d))

As noted in earlier sections, elements of the proposed regulation appear to be inconsistent with the Uniform Trade Secrets and Public Records Act, certain CalOSHA worker safety requirements, and certain federal OSHA and international standards. ACC strongly recommends that DTSC ensure that these inconsistencies are resolved in the final regulation.

E. Nonduplication (Government Code §11349(d))

Two areas of the proposed regulation appear to duplicate other regulatory programs. Section 69501 does not exempt food contact materials from the scope of the regulation, and thus

duplicates the Federal Food, Drug and Cosmetic Act (FFDCA). The federal Food and Drug Administration regulates food contact materials through a comprehensive, science-based regulatory framework. Any DTSC regulation of food contacts materials would necessarily be duplicative of the federal regulatory effort. At a minimum, it is not clear what additional level of health or environmental protection California would confer to food contact materials beyond the extensive and costly federal governmental reviews conducted by highly trained scientific staff with years of experience.

Similarly, the proposed addition of "workers" as a potentially sensitive subpopulation appears to duplicate the existing authority of Cal/OSHA to protect workers from unreasonable exposures to chemicals. California State Plan, §19 OSHA (1970), approved May 1, 1973, and certified August 19, 1977. Per the agreement between the State of California and OSHA, the state plan "applies to all public and private sector places of employment in the state, with the exception of Federal employees, the United States Postal Service, private sector employers of Native American lands, maritime activities on the navigable waterways of the US, private contractors working on land designated as exclusive Federal jurisdiction, and employers that require Federal security clearances." See also, 29 CFR 1952.172. At a minimum, DTSC should explain how the inclusion of workers as a potentially sensitive subpopulation does not duplicate CalOSHA's authority.

Federal Statutes Regulating Chemicals

Abbreviation	Statute	Brief Summary
1. TSCA	Toxic Substances Control Act 15 U.S.C. §§ 2601 – 2695d	• Requires premanufacture notification for all new chemicals not on the TSCA Inventory; authorizes Environmental Protection Agency (EPA) to restrict new chemicals of concern • Authorizes EPA to require periodic reporting of information about chemicals, including manufacturing and use data and health and safety studies • Requires reporting of information that reasonably supports the conclusion of substantial risk • Authorizes EPA to require data submission (akin to premanufacture notice) before companies engage in "significant new uses" of chemicals • Authorizes EPA to issue test rules, and reporting rules for chemicals it finds may pose an unreasonable risk; chemicals may also be tested by industry through voluntary programs under TSCA • Authorizes EPA to require testing to meet good laboratory practice standards and validated protocols • Authorizes EPA to ban or restrict chemicals that pose an unreasonable risk to human health or the environment • Requires certification of TSCA compliance for all imported chemicals • Requires notification to EPA of export of chemicals that have been restricted in the United States • Supports EPA initiatives to prioritize and review chemicals and take regulatory actions to restrict chemicals where EPA deems necessary
2. FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act 7 U.S.C. §§ 136 – 136y	• Requires all pesticide products and their active ingredients, including antimicrobials and certain kinds of preservatives, to be registered prior to sale • Registration requires data showing that the pesticide is effective and does not pose an unreasonable risk to man or the environment; burden of proof is on pesticide manufacturer

Abbreviation	Statute	Brief Summary
		• Authorizes EPA to require testing to meet good laboratory practice standards and validated protocols • Requires registration of producing establishments • Requires annual production reporting • Requires reporting of adverse effects information • Requires certification of FIFRA compliance for imported pesticides • Requires detailed package labeling • Requires notification of export of unregistered pesticides
3. FFDCA	Federal Food, Drug, and Cosmetic Act 21 U.S.C. §§ 301 – 399d	• Prohibits the sale of any food, drug, medical device, or cosmetic that is adulterated or misbranded • Requires premarket approval of food additives, color additives, new dietary ingredients, drugs, and medical devices, including their components, based on a showing that they are safe • Requires producers of food additives that are not "generally recognized as safe" to demonstrate to a reasonable certainty that no harm will result from the intended use of their additives • Broadly defines "food additive" to include small transfers from food packaging materials
4. FQPA	Food Quality Protection Act 110 Stat. 1489, amending FIFRA and FFDCA	• Requires EPA to set tolerances, or maximum safe residue limits, for pesticide residues on foods • Expands EPA authority over food contact substances, e.g. antimicrobials in or on food packaging • Includes special protections for infants and children • Requires EPA to expedite approval of reduced risk pesticides
5. CAA	Clean Air Act 42 U.S.C. §§ 7401 – 7671q	• Sets mandatory performance levels for reducing emissions of toxic air pollutants from various categories of industrial facilities • Requires plans for the prevention of emergency releases to air of highly toxic chemicals • Requires air pollution sources to meet emission limits and obtain permits from EPA or states • Requires reporting and recordkeeping under the permits • Requires phasing out of production and use of ozone-destroying chemicals and encourages the development of "ozone-friendly" substitutes

Abbreviation	Statute	Brief Summary
6. FWPCA / CWA	Federal Water Pollution Control Act (Clean Water Act) 33 U.S.C. §§ 1251 – 1387	• Controls chemical discharges of pollutants to waters through the National Pollutant Discharge Elimination System (NPDES) permit program • Imposes both technology-based standards and effluent guidelines • Operates pretreatment program for industrial facilities that discharge chemicals in waste water into municipal sewer systems
7. SDWA	Safe Drinking Water Act 42 U.S.C. §§ 300f – 300j-26	• Requires EPA to set national health-based standards for chemicals and other contaminants in drinking water • Requires public water systems to test for contaminants and meet drinking water standards; operators must be certified
8. RCRA/ SWDA	Resource Conservation and Recovery Act, amending the Solid Waste Disposal Act 42 U.S.C. §§ 6901 – 6992k	• Gives EPA "cradle-to-grave" authority to control hazardous waste • Requires hazardous waste identification and tracking • Establishes extensive permitting and operating requirements for hazardous waste generators, transporters, treatment facilities, storage facilities, and disposal facilities • Requires corrective action to clean up releases of hazardous wastes or hazardous waste constituents at RCRA-regulated sites • Provides framework for management of non-hazardous solid waste
9. CERCLA / Superfund	Comprehensive Environmental Responsibility, Compensation, and Liability Act 42 U.S.C. §§ 9601 – 9675	• Establishes processes and standards for clean-up of hazardous waste sites and removal and remediation of contaminants • Imposes strict liability for clean-up for potentially responsible parties, including prior owners/operators, entities that arranged for waste disposal, and others, thereby ensuring that care is taken against chemical releases going forward to avoid this liability • Establishes National Oil and Hazardous Substance Pollution Contingency Plan (NCP) • Created the Agency for Toxic Substances and Disease Registry (ATSDR) within CDC Public Health Service, and other offices
10. EPCRA	Emergency Planning and Community Right-to-Know Act 42 U.S.C. §§ 11004 – 11050	• Requires companies to submit detailed annual reports on releases and transfers of certain toxic chemicals (Toxic Release Inventory or TRI reporting); makes reported data publicly available • Requires every community in the United States to be part of a comprehensive emergency response plan; facilities must participate in the planning process

Abbreviation	Statute	Brief Summary
		• Requires companies to maintain material safety data sheets (MSDSs) for hazardous chemicals and to submit the MSDSs or lists of chemicals, and annual inventory of these chemicals, to state and local emergency planning entities and the local fire department (Tier I or Tier II reporting) • Requires immediate notification of accidental chemical releases to state and local emergency planning entities • Requires notification of the presence of high quantities of listed "extremely hazardous substances" to state and local entities
11. PPA / P2 Act	Pollution Prevention Act 42 U.S.C. §§ 13101 – 13109	• Requires companies to file an annual toxic chemical source reduction and recycling report along with TRI report • Requires EPA to consider the effects of its regulations on reduction of pollution production at the source and to coordinate with other agencies to promote source reduction • Creates a Source Reduction Clearinghouse to foster information exchange on source reduction techniques and technical assistance for businesses • Provides grants to states for source reduction programs
12. OSH Act	Occupational Safety and Health Act 29 U.S.C. §§ 651 – 678	• Establishes wide-ranging hazard communication program • Requires manufacturers and importers of hazardous materials to conduct hazard evaluations of the products they manufacture or import • Requires labels and material safety data sheets for hazardous materials at the workplace and accompanying initial shipments to new customers • Requires companies to provide personal protective equipment and training to protect against chemical and other workplace risks • Requires recordkeeping of workplace injuries and illnesses and reporting of serious incidents • Maintains Occupational Chemical Database with EPA • Established the National Institute of Occupational Safety and Health (NIOSH) which researches, inter alia, chemical safety
13. HMTA	Hazardous Materials Transportation Act 49 U.S.C. §§ 5101 – 5127	• Requires identification of potential hazards (including toxicity, flammability, corrosivity, etc.) of transported materials and

Abbreviation	Statute	Brief Summary
		products • Requires hazard communication (shipping papers, package marking and labeling, and vehicle placarding) for various classes of hazardous materials including listed materials, hazardous wastes, and marine pollutants • Specifies packaging safety requirements • Specifies operational and training requirements for transportation of chemicals and hazardous materials by various modes (air, water, road, rail, pipeline) • Administered by Department of Transportation's Pipeline and Hazardous Materials Safety Administration
14. CPSA / CPSIA	Consumer Product Safety Act, as amended by the Consumer Product Safety Improvement Act 15 U.S.C. §§ 2051 – 2089	• Establishes independent Consumer Product Safety Commission • Governs manufacturers (including importers), distributors, and retailers • Sets preference for consensus voluntary private sector standards (e.g. ANSI, ASTM) but authorizes CPSC to impose mandatory standards for product safety • Restricts lead paint and phthalates in children's products or child care articles • Requires labeling, tracking, third party testing and certification for children's products • Requires general conformity certification with each shipment • Requires reporting of product defects or non-compliance with mandatory standards • Enforced by retail, import, and internet surveillance
15. PPPA	Poison Packaging Prevention Act 15 U.S.C. §§ 1471 – 1477	• Requires CPSC to establish standards for special packaging of any household chemical, including fuels, cosmetics, and other substances customarily stored by households, in order to protect children from hazards • Makes alternative labeling option available where child-protective packaging would make the household substance unavailable to elderly or disabled persons
16. FHSA	Federal Hazardous Substances Act 15 U.S.C. §§ 1261 – 1278	• Requires container labeling for hazardous household products to help consumers safely store and use those products and to give

Abbreviation	Statute	Brief Summary
		information on first aid • Authorizes the CPSC to ban certain products that are so dangerous or the nature of the hazard is such that labeling is not adequate to protect consumers
17. FPLA	Fair Packaging and Labeling Act 15 U.S.C. §§ 1451 – 1461	• Requires each package of household consumer commodities to bear a label on which there is information necessary to prevent consumer deception • Administered by the Federal Trade Commission and FDA
18. CSA	Controlled Substances Act 21 U.S.C. §§ 801 – 971	• Restricts the manufacture, import, export, distribution, and use of chemicals which are narcotics or can be used to make narcotics • Administered by the Drug Enforcement Administration in the Department of Justice and by FDA
19. CFATS	Department of Homeland Security Appropriations Act 6 U.S.C. § 121 note	• Authorizes the Department of Homeland Security (DHS) to establish risk-based Chemical Facility Anti-Terrorism Standards for the security of chemical facilities • DHS assigns facilities to one of four risk tiers; different assessment and planning obligations are imposed for the different tiers
20. CWC	Chemical Weapons Convention Implementation Act 22 U.S.C. §§ 6701 – 6771	• Authorizes reporting of information about chemicals that may be used to make chemical weapons • Authorizes international inspection of facilities where chemicals that may be used to make chemical weapons are present • Administered by the Department of Commerce's Export Administration and by the Department of State

Attachment: Estimated Industry Costs

This analysis provides an explanation of the assumptions and estimates used to develop potential industry costs associated with the proposed Safer Consumer Product (SCP) regulations under Title 22 of the California Code of Regulations (CCR 22).

The purpose of this analysis is to present estimates of the direct costs to an entity for the initial preparation of an Alternatives Assessment (AA). Any industry costs that might be incurred for preparing and submitting notifications, petitions, requests, comments, and any additional information or documents requested by the Department are not considered herein.[1] In summary, the completion of one AA will generally range from approximately $1,958 to $15,130. During the first round of Priority Products—i.e., in the first year—it is assumed that small and medium enterprises (SMEs) will prepare one to two AAs and large enterprises will prepare two to three AAs under CCR 22. Therefore, the total cost range to prepare AAs for SMEs and large enterprises is estimated to be approximately $1,958 to $30,261 and $3,916 to $45,391, respectively.

Industry Costs per Alternative Assessment

As shown in Table 1, three employee categories of labor (clerical, technical, and managerial) were used in this cost analysis. Rates and hours were assigned based on the estimated costs to prepare and submit a Premanufacture Notice (PMN) Form to U.S. EPA Office of Toxic Substances as part of the implementation of Section 5 of the Toxic Substances Control Act (TSCA).

Table 1. Estimated Industry Labor Costs per Alternative Assessment (AA)

	Clerical	Technical	Managerial	Total
Hours[a]	8 - 40	27 - 67	8 - 37	43 - 344
Cost per Hour[b, c]	$17	$42	$85	-
Total Cost	$136 - 678	$1,144 - 11,316	$678 - 3,136	**$1,958 - 15,130**

[a] Assumed the hours to prepare and submit PMN form would be comparable to the hours to prepare and submit an AA.
[b] Costs include direct salaries and benefits, but do not include corporate overhead.
[c] A specific inflation rate was calculated to account for the price increase from the 1979 Arthur D. Little, Inc. estimates.
Sources: Estimated Costs of Preparation and Submission of Reproposed PMN Form (Arthur D. Little, Inc. 1979) and Price Indexes for Gross Domestic Product (U.S. Department of Commerce 2012a)

For each alternative chemical being considered, responsible entities are also required to evaluate the toxicological and environmental endpoints to identify any potential adverse public health and/or environmental impacts. The generation of this data for a single chemical could be costly for responsible entities. A basic set of test data can cost approximately $200,000 per chemical

[1] Costs associated with providing the Department with any of the following have not been included in the industry cost burdens estimated in this report and could pose additional costs for responsible entities: Priority Product Notifications; Priority Product Removal Notifications; Priority Product Replacement Notifications; Priority Product Cease Ordering Notifications; Alternatives Analysis Threshold Exemption Notifications; Chemical of Concern Removal Notifications; Trade Secrets; Petitions; and any other subsequent information requested by the Department.

(U.S. EPA 1997). Table 2 below summarizes other potential testing costs that might be associated with evaluating alternative chemicals.[2]

Table 2. Potential Toxicological Test Costs for Alternative Chemicals

Test Type	Associated Costs *
Carcinogenicity	$1.1 million (for a mouse study) to ~$5 million
Reproductive Toxicity	$700,000 to $1,000,000
Developmental Toxicity	$250,000 to $300,000
Neurotoxicity	$700,000 to $1,000,000
Immunotoxicity	~$86,000
Endocrine Screening	$400,000 to $1 million
Respiratory Toxicity	$82,000
Acute Oral Toxicity	$4,000 to $32,000
Acute Inhalation Toxicity w/ Histopathology	$25,000
90-day Subchronic Oral Toxicity	$150,000 to $200,000
2-year Chronic Oral Toxicity	$750,000 to $1 million
Mutagenicity Screen	$4,000 to $6,000

Industry Costs per Entity

Alternatives Assessments must be submitted by "responsible entities," which are defined under the proposed SCP regulations to include manufacturers, importers, distributors, retailers or any other entity that has a contract with an importer, distributor, or retailer. Assumptions about the number of entities were based on available data on the number of firms by employment sizes for the United States, as well as ICF estimates.

Of particular concern are the financial impacts that the proposed SCP regulations might have on SMEs, which make up approximately 98% of the affected firms. A universally accepted definition of an SME does not exist within the U.S. government (USITC 2010). However, according to Article 11 § 69311 of the DTSC September 2010 draft SCP proposed regulations, a small business has 25 or less employees.[3] Using the number of employees as basic classification criteria, the U.S. Small Business Administration (SBA) defines a SME to be a firm with less than 500 employees. For the purposes of this analysis, it is assumed that small enterprises have less than 20 employees, medium enterprises have between 20 and 500 employees, and large enterprises have more than 500 employees.

As shown in Table 3, small and medium enterprises are assumed to be responsible for a range of 1 to 2 chemicals of concern and therefore responsible for preparing and submitting 1 to 2 AAs. Moreover, large enterprises are assumed to be responsible for a range of 2 to 3 chemicals of concern and therefore 2 to 3 AAs. In total, it is estimated that the identified entities will need to

[2] For further detail on estimated costs for toxicological tests, refer to Appendix B of the report, "Potential Costs to the State of California Associated with Implementing the Proposed Safer Consumer Product Regulations under CCR 22."

[3] Article 11 § 69311 has since been deleted from the text of proposed regulations.

prepare between 1 and 3 AAs under CCR 22, costing approximately between $1,958 and $45,391.

Table 3. Estimated Industry Labor Costs by Entity Size

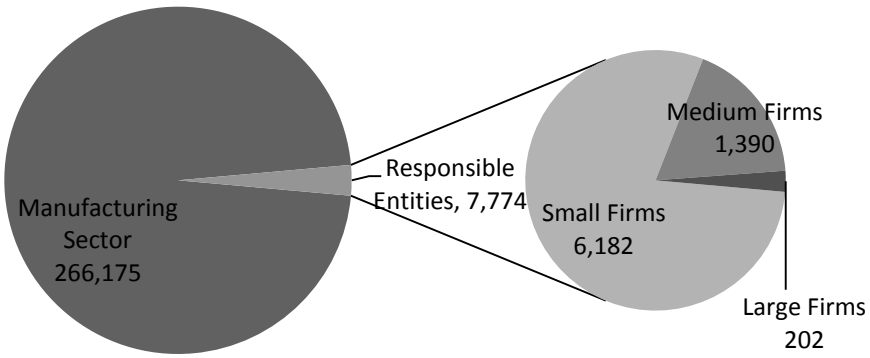
	No. of AAs	Cost
Small Enterprises		
Assuming 1 chemical per entity	1	$1,958 – $15,130
Medium Enterprises		
Assuming 1 to 2 chemicals per entity	1 – 2	$1,958 – $30,261
SMEs Subtotal	***1 – 2***	***$1,958 – $30,261***
Large Enterprises		
Assuming 2 to 3 chemicals per entity	2 – 3	$3,916 – $45,391
All Enterprises	**1 – 3**	**$1,958 – $45,391**

Sources: Estimated Costs of Preparation and Submission of Reproposed PMN Form (Arthur D. Little, Inc. 1979); Price Indexes for Gross Domestic Product (U.S. Department of Commerce 2012a); and ICF estimates

Responsible Entities

As shown in Figure 1, approximately 3% of firms in the manufacturing sector are estimated to be responsible entities under CCR 22. These firms include 6,182 small enterprises, 1,390 medium enterprises, and 202 large enterprises. Figure 2 shows that approximately 13% of firms in the wholesale trade sector are estimated to be responsible entities under CCR 22.[4] These firms include 33,284 small enterprises, 6,168 medium enterprises, and 807 large enterprises.

Figure 1. Responsible Entities in the Manufacturing Sector

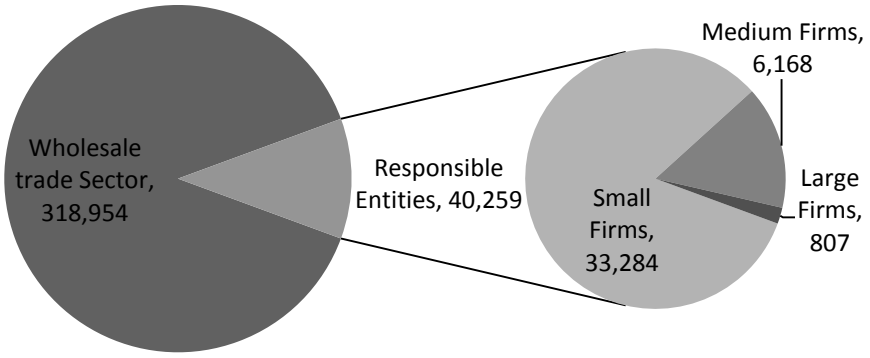


[a] Assumed the CCR 22 would impact the following industries by NAICS code: 339932,

[4] According to the U.S. Department of Commerce, the Wholesale Trade sector is comprised of establishments engaged in wholesaling merchandise, generally without transformation, and rendering services incidental to the sale of merchandise. The merchandise described in this sector includes the outputs of agriculture, mining, manufacturing, and certain information industries, such as publishing (2012b).

31522, 31523, 315291, 325612, 325611, 325510, 325620, 337122, and 337122.
Sources: U.S. Department of Commerce 2009 County Business Patterns (U.S. Department of Commerce 2009) and ICF estimates

Figure 2. Responsible Entities in the Wholesale Trade Sector



[a] Assumed the CCR 22 would impact the following industries by NAICS code: 423990, 424210, 42432, 424490, 4246, and 4248.
Sources: U.S. Department of Commerce 2009 County Business Patterns (U.S. Department of Commerce 2009) and ICF estimates

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Potential Costs to the State of California Associated with Implementing the Proposed Safer Consumer Product Regulations under CCR 22

Prepared
by
ICF International

July 26, 2012

ICF International prepared this report under a contract with the American Chemistry Council.
The views and findings expressed herein are those of the ICF authors.

Table of Contents

Executive Summary

The following summary presents the estimated costs that would be incurred by the California Department of Toxic Substances Control (DTSC) to implement the revised draft Safer Consumer Product (SCP) regulations as published May 2012.[1] These regulations require DTSC to identify chemicals in consumer products based on potential health and environmental impacts, and to establish the regulatory responses that DTSC can take to limit exposure or reduce the level of hazard posed by these chemicals in consumer products. The following broad conclusions can be drawn from this cost analysis:

- **Annual DTSC implementation costs are estimated to range from about $9 to $27.2 million in the first six years, depending on the assumed scope of the SCP program**. These costs could be even higher if more chemicals in products are reviewed by DTSC, if more industry consortia or responsible entities submit Alternatives Assessment reports for review by DTSC, or if additional regulatory actions are pursued.

- **Over time, annual costs for the program are expected to increase as the cumulative number of priority chemicals and products regulated by DTSC grows.** DTSC's SCP program will be an ongoing effort to continually assess and regulate additional priority chemicals and products. Thus, as the total number of regulated chemicals and products grows, it is likely that the cumulative burden on DTSC will also trend upward over time.

The draft regulation does not specify the process and procedures that DTSC will follow to pare down the universe of chemicals into those that will be the focus of the regulatory process. In order to estimate the cost to DTSC of implementing the program, ICF has assumed that DTSC will take a number of steps to identify chemicals of concern. First we have assumed an initial "universe" of 3000 chemicals of potential interest to the DTSC. From this number we assumed that approximately 10% would be classified as chemicals of concern and that the levels of interest for this set of chemicals would be found in approximately 150 products. As noted in the draft regulation, DTSC anticipates that as many as 5 products could be considered as Priority Products in the first year of the program. ICF has assumed that once the program is fully active, an additional 6 products per year could be classified as priority across the next five years of the program. Thus, we have assumed that DTSC will need to review and assess 35 products during the first six years of the program. In addition we have assumed that the regulation will result in the formations of 100 industry consortia to generate Alternative Assessment reports and that 50% of the products identified as priority products will ultimately require regulatory determinations and/or actions by DTSC. These assumptions are presented in Table E-1.

The estimated costs to DTSC of implementing the proposed SCP regulations are shown in two ways below. Table E-2 shows DTSC costs by Article of the proposed regulation, along with additional costs that would be required to maintain the program on an ongoing basis. Table E-3 presents annual DTSC implementation costs for Year 1 through Year 6.

[1] Accessed October 25, 2010 at: http://www.dtsc.ca.gov/LawsRegsPolicies/upload/SCPA-Regs_APA-format-9-07-10-rev-9-12.pdf

Table E-1: ICF Assumptions for Implementing the May 2012 Program

Chemical and Product Assumptions	**Program**
Number of chemicals on "Initial Chemicals of Concern List"	3,000
Number of Priority Chemicals	300
Number of product categories listed as "under consideration"	150
Number of Priority Products identified in the first 6 years of Program	35
Alternatives Assessment and Regulatory Response Assumptions	
Number of consortia submitting AA reports	100
Percentage of priority products requiring regulatory determinations/actions	50%

Table E-2: Summary of DTSC Implementation Costs by Article

	Program
Costs by Article	
Article 2: Chemical of Concern Prioritization Process	$25,190,000
Article 3: Product Prioritization Process	$9,350,000
Article 4: Petition Process	$15,000,000
Article 5: Alternatives Assessments	$15,320,000
Article 6: Regulatory Responses	$2,550,000
Article 9: Audits	$360,000
Article 10: Confidentiality of Information	$1,440,000
Additional program costs	
General program administration	$4,860,000
Data management system development and hardware/software	$1,700,000
Data system upkeep and management	$2,400,000

Table E-3: Total Annual Costs across the first six years of the Program

	Year 1	**Year 2**	**Year 3**	**Year 4**	**Year 5**	**Year 6**
Program	$19,170,000	$14,581,667	$9,056,667	$27,236,667	$14,641,667	$9,966,667

As shown, annual costs are estimated to range from about $9 to $27.2 million under this Program. Thus, at the upper end of the range, DTSC's own estimate of annual program costs of approximately $10 to $13 million[2] is a little below the cost estimates made for the newest draft regulations in this assessment, although the scope of the program DTSC estimates implementing for that cost is not known. In addition, program costs are expected to increase over time as the number of priority chemicals and products cumulates.

[2] See DTSC's 45-day notice issued for the SCPA regulations, Department reference number R-2010-05.

1. Introduction

In December 2010, ICF International prepared and published an analysis of the fiscal implications that might be associated with the implementation of the Safer Consumer Product (SCP) regulations under Title 22 of the California Code of Regulations (CCR 22) titled *Potential Costs to the State of California Associated with Implementing the Proposed Safer Consumer Product Alternatives Regulations under CCR 22*.[3] In (October 2011 and in) May 2012, some of the proposed requirements of the Safer Consumer Product (SCP) regulations were updated by the State of California. This paper considers these changes and represents a revision of the prior fiscal implications analysis.

The California Department of Toxic Substances Control (DTSC) is proposing the SCP regulation in order to (a) identify and prioritize chemicals or chemical ingredients in consumer products that may be considered of concern; (b) evaluate chemicals of concern in consumer products, and their potential alternatives, to determine how best to limit exposure or reduce the level of hazard posed by priority chemicals; and (c) establish the regulatory responses that DTSC may take.

Under these regulations, DTSC would identify chemicals of concern and prioritize those chemicals based on their potential health and environmental impacts. A list of priority products containing chemicals of concern would be created as well. Product prioritization based on analyses of adverse impacts on public health and the environment would also consider implications from a life cycle perspective. Manufacturers of priority products would conduct alternative assessments to determine whether "safer", feasible alternatives could be placed on the market. DTSC's major responsibilities would include:

- Identifying a list of Chemicals of Concern (Article 2);
- Identifying a list of Priority Products (Article 3);
- Sharing information about Priority Chemicals and Products with manufacturers and consumers (Articles 2 and 3);
- Receiving and reviewing petitions for new Chemicals of Concern and/or Products (Article 4);
- Preparing and distributing guidance to manufacturers (in-state and out-of-state) to assist certified assessors performing Alternatives Assessments (Article 5);
- Reviewing Alternatives Assessments and determining regulatory responses (Articles 5 and 6);
- Reviewing documentation required as a result of regulatory response determinations (Article 6);
- Conducting audits of Alternative Assessments (Article 9);
- Reviewing and processing claims of confidentiality and trade secrets (Article 10); and
- Conducting general program administration.

[3] Accessed October 25, 2010 at: http://www.dtsc.ca.gov/LawsRegsPolicies/upload/SCPA-Regs_APA-format-9-07-10-rev-9-12.pdf

1.1. Key Features of the of May 2012 Draft Regulations

The following provides a summary of the key features of the Revised Informal Draft 2012 regulations:[4]

- Much larger Chemicals of Concern list - The Chemicals of Concern list would consist of 3,000 Chemicals upon adoption of regulations.
- Significant Acceleration of Program –
    - The Chemicals of Concern list would take effect immediately instead of over 12 months as initially proposed.
    - Priority Products would be identified 6 months after the regulations take effect.
    - Once a product is listed on the Priority Product List, the product manufacturer has about 2 months to respond to DTSC whether it manufactures such a product or the product does not exceed threshold levels.
- Broader Scope – unlike earlier proposals, the regulations no longer limit Priority Products to children's products, personal care products, and household cleaning products, although the Draft Regulations may prioritize listing based on these principles.[5]
- Smaller Initial Priority List – DTSC states in the May revision that initially—i.e., in the first year—it will identify no more than five Priority Products, although others can be added over time.
- Not "required" to submit CBI – The DTSC might still request confidential business information regarding certain chemical and product information, but the responsible entities would not be "required" to disclose it at the onset for the product prioritization process.
- Streamlined Alternatives Assessment – Requirements to fill-in information gaps before an Alternatives Assessment is finalized have been eliminated. Deadlines are clearly defined for the completion of preliminary and final Alternative Assessment reports.
- Exemptions - The new default *alternative analysis threshold* is 0.01% for Chemicals of Concern exhibiting nine specific hazard traits and stays the same (0.1%) for all other chemicals of concern.
- Preventing Disclosure of CBI - The current May 2012 Draft regulations still require the manufacturer or other responsible party to obtain an interim notice to prevent disclosure of a claimed trade secret if no decision is reached within a 30-day period.

This report estimates the costs to state government for establishing and implementing this new toxic substances control program, and also identifies some opportunities for mitigating these costs. Specifically, the fiscal burden associated with DTSC's major responsibilities under Articles 2-6, 9 and 10 are estimated in this report; any state costs that might be incurred for implementation of Article 7 (Dispute Resolution) and Article 8 (Accreditation and Qualification Requirements for Performance of Alternatives Assessments) are not considered herein.[6] Because the current proposed regulations are still somewhat vague with regard to the scope of implementation, as noted throughout this analysis, a number of assumptions were required to evaluate the burdens on government. The remainder of this

[4] DTSC. (2011). *Safer Consumer Products --- Informal Draft Regulations: Significant Changes*. Department of Toxic Substances Control. October 31, 2011. Available online: <http://dtsc.ca.gov/upload/SCPRegulationsInformal-DraftSignificantChanges.pdf>

[5] Note that the September 7, 2010 draft on which the initial (December 2010) ICF analysis was based had a broader scope similar to the current 2012 version. The November 2010 draft of the regulations narrowed the scope but the December 2010 ICF analysis did not consider this narrowing of scope in its cost analysis.

[6] In addition, other costs, such as enforcement costs, unintended costs (e.g., litigation costs), and the potential cost to the State of California if the price of priority products purchased by the state increases as a result of the regulations, have not been included in the government cost burdens estimated in this report and could pose an additional cost for the State of California.

paper discusses the cost implications of the May 2012 draft regulation requirements for DTSC, and is organized as follows:

- Section 2 presents costs associated with implementation of Articles 2 and 3 (development of chemical and product lists);
- Section 3 addresses costs associated with implementation of Articles 5 and 6 (alternative assessments and regulatory responses);
- Section 4 estimates costs associated with implementation of Articles 4, 9, and 10 (petitions, audits, and confidentiality); and
- Section 5 presents a summary of costs estimated herein.

2. Chemical of Concern and Priority Product Lists (Articles 2 and 3)

Because the draft regulations do not specify how many chemicals and products DTSC will review or include on its "Priority" lists, broad assumptions are required regarding the scope of the program in order to conduct a cost analysis. Thus, for the purposes of this scoping analysis, assumptions were made as to how many chemicals and products will be initially reviewed and identified as "priority." These assumptions affect the projected cost for DTSC in implementing these Articles of the SCP regulations, and thus, to the extent that the program scope is different than what is assumed herein, so too will the cost be different.

ICF's scoping assumptions are provided in Section 2.1, followed by cost estimates in Section 2.2.

2.1. Scoping Assumptions

Assumptions about the number of chemicals and products addressed in the implementation of the SCP regulation were based on research into related programs in California and at the federal level, as well as available data on the number of consumer products in the United States.

Table 1 shows assumptions regarding the scope of the SCP regulations for the current program scope.

For the development of the initial chemical lists, ICF assumed that about 3,000 chemicals would be initially reviewed for listing.[7] Of those chemicals under consideration, approximately ten percent were assumed to be selected as "priority chemicals." This calculation was based on existing lists of very high concern chemicals,[8] as well as a general assumption about the overall risk profiles of the chemicals under consideration.

For the development of the initial product lists, ICF assumed that a total of 300 consumer product categories would be initially reviewed for listing. This number is based on a review of the U.S. Census Bureau's North American Product Classification System (NAPCS) product lists which was used to identify those product categories with consumer applications.[9] From those product categories, around

[7] Safer Consumer Products – Informal Draft Regulations. Significant Changes, Available online: http://dtsc.ca.gov/upload/SCPRegulationsInformal-DraftSignificantChanges.pdf . Last accessed June 4, 2012.

[8] Examples include the candidate list of Substances of Very High Concern from the European Chemicals Agency (ECHA) (http://echa.europa.eu/chem_data/authorisation_process/candidate_list_en.asp).

[9] Products were identified by their corresponding codes under the North American Industrial Classification System (NAICS) at the six-digit level. As explained by the U.S. Census Bureau: "NAICS is a two- through six-digit hierarchical classification system, offering five levels of detail. Each digit in the code is part of a series of progressively narrower categories, and the

150 products were assumed to be listed as "products under consideration," and then 35 products were assumed to be selected as "priority."

Table 1. Assumptions Regarding the Scope of the SCPA Regulations

Chemical and Product Assumptions	**Program**
Number of chemicals on "Initial Chemicals of Concern List"	3,000
Number of Priority Chemicals	30
Number of product categories listed as "under consideration"	150
Number of Priority Products identified in the first 6 years of Program	35
Alternatives Assessment and Regulatory Response Assumptions	
Number of consortia submitting AA reports	100
Percentage of priority products requiring regulatory determinations/actions	50%

In addition to assumptions about the number of chemicals and products reviewed and listed, assumptions were also required about the effort required by DTSC staff to develop these lists.

Table 2 presents assumptions regarding the level of effort (shown in hours and full-time equivalents, or FTEs) on a "per chemical" or "per product" basis. Assumptions were developed based on the past experience of ICF toxicologists in reviewing chemical and product information. Because of the multiple components and complex manufacturing and assembly processes of many products today, a substantial effort is assumed to be required to determine whether a certain product should be listed as priority. For example, a multidisciplinary team including toxicologists, chemists, engineers, economists, and other professionals might be required to make such a determination. Further description of the effort to make a listing determination per product is provided below.

Table 2. Assumptions Regarding the Effort Required to Develop Chemical and Product Lists

	Hours	**FTE**
Initial Chemical List Development		
Hours *per chemical* to review technical material and determine whether to list as a "Chemical of Concern"	40	0.02
Hours *per chemical* to review technical material and determine whether to list as a "priority chemical"	60	0.04
Initial Product List Development		
Hours *per product* to review technical material and determine whether to list as a "priority product"	200	0.10
Hours *per product* to review technical material and determine whether to list as a "priority product"	500	0.24
Both Chemical and Product List Development		
Hours *per list* to solicit and respond to public comments	1041	0.50

more digits in the code signify greater classification detail. The first two digits designate the economic sector, the third digit designates the subsector, the fourth digit designates the industry group, the fifth digit designates the NAICS industry, and the sixth digit designates the national industry." See: http://www.census.gov/eos/www/naics/faqs/faqs.html#q5

Figure 1. The Definition of a "Product"

The burden to DTSC of reviewing products for listing as "under consideration" and "priority" may additionally depend on the level of product the Department decides to review. For example, using a six-digit NAICS/NAPCS level product definition means that DTSC would have to review multiple consumer product types to list one six-digit NAICS/NAPCS product.* As an example, the product category "Toilet Preparation Manufacturing" (NAICS/NAPCS No. 325620) includes:

- Shaving preparations
- Perfumes, toilet waters, and colognes
- Shampoos
- Hair and scalp conditioners
- Hair creams, pomades, sprays, and rinses
- Hair mousse, perms, and coloring preparations
- Creams, lotions, and oils
- Dentifrices, mouthwashes, gargles, and rinses
- Other cosmetics and toilet preparations

2.2. Estimated DTSC Costs

FTE costs associated with the listing of chemicals and products of concern are estimated below. These program costs are assumed to be experienced between January of the first year and December of the third year, according to the proposed schedule. This analysis assumes that DTSC will rely primarily on public information and data submitted by manufacturers to make its listing determinations, and thus, that DTSC does not incur extramural costs for the generation of toxicity test data, such as tests for acute and chronic toxicity, developmental/reproductive toxicity, mutagenicity, and ecotoxicity. Such testing can be costly, as described in Appendix B.

Table 3 below presents the estimated FTE costs associated with DTSC's implementation of Articles 2 and 3 of the proposed SCPA regulations.

Table 3. Estimates of Program FTEs and Associated Cost for Articles 2 and 3

	Program	
	FTE	**Cost***
Article 2: Chemical Prioritization Process		
Develop initial list of Chemicals of Concern	57.7	$10,010,000
Solicit and respond to public comments; finalize list of Chemicals of Concern	0.5	$90,000
Develop initial list of Priority Chemicals	86.5	$15,010,000
Solicit and respond to public comments; finalize list of Priority Chemicals	0.5	$90,000
Article 2 Subtotal	**145.2**	**$25,190,000**
Develop initial list of Priority Products	28.8	$5,000,000
Solicit and respond to public comments; finalize list of Priority Products	0.5	$90,000
Develop initial list of Priority Products	24.0	$4,170,000
Solicit and respond to public comments; finalize list of Priority Products	0.5	$90,000
Article 3 Subtotal	**53.9**	**$9,350,000**
INITIAL LIST DEVELOPMENT TOTAL	**199.1**	**$34,530,000**

Totals may not sum due to independent rounding.
* Assumptions regarding the average cost per FTE are described in Appendix A.
† Article 3 total does not include costs associated with the receipt and review of priority product notification reports.

3. Alternatives Assessments and Regulatory Responses (Articles 5 and 6)

As noted previously, because the draft regulations do not specify how many chemicals and products DTSC will include on its "Priority" lists beyond the first year, it is not possible to know precisely how many businesses will be affected. Thus, in order to conduct a cost analysis, broad assumptions are required regarding the scope of affected businesses. For the purposes of this scoping analysis, assumptions were made as to how many businesses/consortia will be required to submit notifications, perform alternative assessments, and be subject to regulatory responses. These assumptions affect the overall projected cost for the DTSC in implementing the proposed SCP regulations, and thus, to the extent that the number of affected businesses is different than what is assumed here, so too will the cost be different.

ICF's scoping assumptions are provided in Section 3.1, followed by cost estimates in Section 3.2.

3.1. Scoping Assumptions

Assumptions about the number of reports that DTSC would receive and review were based on available data on the number of consumer products and associated manufacturers in the United States, as well as ICF estimates. Reports, such as Alternatives Assessments (AAs), must be submitted by "responsible entities," which are defined under the proposed SCP regulations to include manufacturers, importers, distributors, retailers or any other entity that has a contract with an importer, distributor, or retailer. Although responsible entities up and down the supply chain will be subject to the proposed requirements, businesses are allowed to meet the requirements through consortia such as trade associations, partnerships, and other similar arrangements. Thus, for the purposes of this report, it is assumed that two consortia will submit AAs per priority product, with each AA representing a

compilation of information from affected businesses belonging to those consortia.[10]

Table 4 shows flow-down assumptions regarding the number of reports received by DTSC under the May 2012 SCP proposed regulation. In addition to assumptions about the number of AA reports submitted and the number of regulatory determinations, assumptions were also required about the effort required by DTSC staff to review these reports and make these determinations.

Table 4. Key Assumptions Regarding the Number of Reports Received and Regulatory Responses Required by the Proposed SCP Regulation

	Program
Alternatives Assessment Assumptions	
Number of consortia submitting notifications and AA reports	40
Percentage of manufacturers submitting *alternatives analysis threshold* exemption requests	10%
Regulatory Response Assumptions	
Percentage of priority products requiring regulatory determinations/actions	50%
Percentage of manufacturers producing priority products subject to regulatory response requirements	50%

Table 5 presents assumptions regarding the level of effort (in hours and FTEs) on a per report or per regulatory determination basis. Assumptions were developed based on expert input and existing burden estimates for federal chemical programs with some similar components (EPA's TSCA Inventory Update Reporting [IUR][11] and Significant New Use Rules [SNURs] [12]). It might be expected that costs will decrease because of economies of scale and build up of organizational knowledge over time; however, for this analysis costs are assumed to be constant over the timeframe consider by this report.

[10] It is likely that many more businesses will be impacted in a myriad of ways by these proposed regulations. For the purposes of estimating costs to DTSC, however, it was only necessary to determine the number of businesses that might be submitting reports, notifications, or requests to DTSC, and thus the number of such documents that DTSC must review and process.

[11] EPA. (1999). Economic Analysis of Proposed Amendments to the TSCA Section 8 Inventory Update Rule. March 1, 1999.

[12] EPA. (2008). Information Collection Request, TSCA Section 5(a)(2) Significant New Use Rules for Existing Chemicals. EPA ICR No. 1188.08; OMB Control No. 2070-0038.

Table 5. Key Assumptions Regarding the Level of Effort Required to Review Reports and Make Regulatory Determinations

	Hours	FTEs
Alternatives Assessment		
Hours to prepare guidance materials to assist persons in performing AAs	1,040	0.50
Hours *per report* to review AA notification report and Preliminary AA report	20	0.01
Hours *per report* to review AA Work Plans	20	0.01
Hours *per detailed (final) report* to review and issue notice of completion or deficiency	1,000	0.48
Hours *per detailed (final) report* to review revised report	40	0.02
Hours *per detailed (final) report* to determine if regulatory response is required	40	0.02
Hours *per request* to review *alternatives analysis threshold* exemption requests	40	0.02
Regulatory Responses		
Hours *per product* to determine regulatory response*	700	0.34
Hours *per report* to review additional data requested for evaluation of AA Reports	20	0.01
Hours *per report* to review End-of-Life Management reports	20	0.01
Hours *per request* to review exemption submissions from regulatory response requirements and issue notice of grant/deny	40	0.02
Hours *per report* to review notification reports from responsible entities of applicability and completion of regulatory response	220	0.11
Hours *per year* to develop and update quarterly a Regulatory Response Report	350	0.17

* This includes requests for any supplemental information, making the appropriate regulatory determination, soliciting and responding to comments on the proposed regulatory response, and finalization and notice of the final determination.

3.2. Estimated DTSC Costs

This section presents estimated costs to DTSC associated with the receipt and review of AA reports and related documentation (such as exemption requests), as well as the burden associated with making regulatory determinations and reviewing related documentation (such as required reports, exemption requests, comments, status updates and other types of documents).

Several important limitations must be noted. First, these costs are highly variable depending on the number of alternative assessments received and the number and type of regulatory determinations that DTSC decides to make. While broad assumptions have been made to this effect, the scope of the implementation of these Articles is uncertain, and thus costs could be substantially different than what are estimated here if the extent of implementation is also different.

Second, although there is an estimated time frame from the first notification through the completion of the AA, uncertainty remains high in terms of the time involved in reviewing and oversight of the regulatory responses. Thus, the timeframe for incurring these costs is uncertain. Preliminary AA reports are due 180 days after the priority product is listed or 120 days from when the Work Plans are due. However, extensions of up to 90 days may be requested and granted under special circumstances. Based on the proposed regulations, it might reasonably be assumed that preliminary AA Reports largely will be submitted by 6 months and final AA reports within one to two years (by 18 months and not to exceed 30 months) following DTSC's approval of the preliminary report. It is also not known how long after the submission of the AA Reports regulatory responses will be determined, though the Department will be required to issue a notice of compliance, disapproval or ongoing review within 60 days after

submission of the final AA report. Thus, it is difficult to attribute the costs to DTSC of reviewing AA Reports and making regulatory response determinations to individual years. That said, the finalization of an initial priority product list—and the assumption that about 35 products will be on it by the end of the sixth year—has the potential to require a substantial number of AA Reports and associated regulatory responses in the timeframe of about two years following the publication of the priority product list.

Table 6 below presents the estimated FTE costs associated with DTSC's implementation of Articles 5 and 6 of the proposed SCPA regulations. As mentioned above, the majority of these costs are assumed to be incurred in the two years following the publication of the initial priority product list; costs estimated below are not annual costs. Program costs by year are estimated in Section 5 of this report.

Table 6. Estimates of Program FTEs and Associated Cost for Articles 5 and 6

	Program	
	FTE	**Cost***
Article 5: Alternative Assessments		
Prepare guidance materials to assist persons in performing AAs	0.5	$90,000
Review AA Work Plans	0.7	$120,000
Review notification and Preliminary AA reports	0.7	$120,000
Review *alternative analysis threshold* exemption requests	17.6	$3,050,000
Review Final AA reports	68.9	$11,950,000
Article 5 Subtotal	***88.4***	***$15,320,000***
Article 6: Regulatory Responses		
Prepare regulatory response determination	5.9	$1,020,000
Review reports and additional information required by regulatory determinations	0.2	$40,000
Review exemption requests	0.1	$20,000
Review notification reports on applicability and completion of regulatory responses	8.4	$1,460,000
Develop annual Regulatory Response Report	0.0	$10,000
Article 6 Subtotal	**14.7**	**$2,550,000**
ARTICLE 5 & 6 TOTAL	**103.0**	**$17,870,000**

Totals may not sum due to independent rounding.
* Assumptions regarding the average cost per FTE are described in Appendix A.

4. Petitions, Audits, and Confidentiality (Articles 4, 9, and 10)

This section estimates the annual burden to DTSC associated with petitions, audits, and requests for confidentiality under the proposed SCP regulations. Article 4 of the SCP regulations allows for any person to petition DTSC in order to evaluate chemicals or products for inclusion in or removal from the program, while Article 9 enables DTSC to perform audits on, but is not limited to, AAs, AA Reports, information related to notifications and implementation of regulatory responses. Article 10 allows any person to submit information confidentially to DTSC. The assumptions used affect the estimated cost of the program and thus, the costs of the program will vary depending on the difference in scope from those assumptions stated below.

ICF's scoping assumptions are provided in Section 4.1, followed by cost estimates in Section 4.2.

4.1. Scoping Assumptions

Assumptions were used to determine the number of petitions and audits processed annually, as well as the number of confidentiality claims that would accompany report submissions. These assumptions were based upon knowledge of similar processes and expected involvement of the public and manufacturers regulated under the program. Table 7 lists the assumptions used for this section. Based upon the resources required to perform an audit and the logistics involved, a small number of audits are expected to be performed each year by DTSC. ICF also assumed that all reporting parties will choose to divulge their chemicals under a confidential or trade-secret agreement due to the intellectual property nature of consumer products. This assumption is consistent with EPA estimates that about 95% of pre-manufacture notices for new chemicals contain information that is claimed as confidential.[13] It is also expected that a significant number of requests for information under the California Public Records Act (CPRA) will be received, as many as 50 per year, using the number of federal Freedom of Information Act (FOIA) requests for Region 9 (which includes California) as a guide.[14]

Table 7. Assumptions about Number of Petitions, Audits, and Confidential Requests

	Program
Petition Process	
Number of petitions received per year for the 6 years assessed herein	150
Percentage of petitions granted	50%
Audits	
Number of reports audited each year	7
Confidentiality of Information	
Percentage of affected businesses submitting claims of confidentiality or trade secrets	100%
Number of requests under CPRA received per year	50

By expanding upon the assumptions about the number of processes expected, assumptions were made about the level of effort required by DTSC staff to complete these tasks.

Table 8 presents assumptions regarding the level of effort (shown in hours and full-time equivalents, or FTEs) on a per task basis for Articles 4, 9, and 10 of the proposed regulations. Assumptions were developed based on expert input.

[13] EPA. (2006). U.S. Government Accountability Office, Testimony before the Committee on Environment and Public Works, U.S. Senate, Chemical Regulation, Actions Are Needed to Improve the Effectiveness of EPA's Chemical Review Program. Statement of John B. Stephenson, Director, Natural Resources and Environment. GA-06-1032T. Available online at: http://www.gao.gov/new.items/d061032t.pdf

[14] Nearly 600 FOIA requests were received in 2009 for Region 9, which includes California as well as Arizona, Hawaii, Nevada, American Samoa, and Guam (http://www.epa.gov/foia/docs/2009report.pdf). Substantially fewer CPRA requests are assumed be received in California related to this rulemaking.

Table 8. Assumptions Regarding the Level of Effort Required for Handling Petition Process, Audits, and Reviewing of Confidentiality Requests

	Hours	FTE
Petition Process		
Hours *per petition* to prioritize, conduct technical review, request additional information, and prepare notification	120	0.06
If petition is granted, hours *per chemical or product* to add and prioritize chemical and/or product according to Articles 2 and 3	200	0.1
Audits		
Hours *per audit* to audit preliminary and final AA reports and issue notification of findings	100	0.05
Confidentiality of Information		
Hours *per claim* to review claims of confidentiality	40	0.02
Hours *per claim* to review claims of trade secret protection	40	0.02
Hours *per request* to notify submitters of requests under the California Public Records Act	1	< 0.01

4.2. Estimated DTSC Costs

Costs associated with the petition and audit processes, as well as the handling of confidential information are estimated below. These costs are assumed to be experienced annually for the duration of the program as it continues and expands in scope to accommodate more chemicals, potentially increasing in the out-years as the number of priority chemicals and products also increases.

Table 9 below presents the estimated FTE costs associated with DTSC's implementation of Articles 4, 9, and 10 of the proposed SCPA regulations.

Table 9. Estimates of Program FTEs and Associated Annual Cost for Articles 4, 9 and 10

	Program	
	FTE	**Cost***
Article 4: Petition Process		
Review, prioritize, and conduct technical reviews for petitions received (annually)	7.2	$1,250,000
Add and prioritize chemicals and products to listings subject to Articles 2 and 3 (annually)	7.2	$1,250,000
Article 4 Subtotal	***14.4***	**$2,500,000**
Article 9: Audits		
Audit Preliminary and Final AA and issue findings (annually)	0.3	$60,000
Article 10: Confidentiality of Information		
Review and respond to claims of confidentiality, trade secret, and requests under CPRA (annually)	1.4	$240,000

Totals may not sum due to independent rounding.

* Assumptions regarding the average cost per FTE are described in Appendix A.

5. Summary of DTSC Costs for Implementation of Proposed SCP Regulations

The proposed SCP regulations include initial activities to get the program up-and-running, and ongoing activities to support the program's goals, as described in the sections above. This section summarizes those costs and organizes them by the years in which they are assumed to be incurred.

This analysis has attempted to estimate the major costs to DTSC associated with implementation of the proposed SCP regulations. In addition to those costs estimated in previous sections of the report for each Article of the regulation, other costs will also be incurred related to general program administration, such as posting documentation on DTSC's website or evaluating deadline extension requests, and is assumed to be managed annually by six FTEs. Likewise, the creation of a data management system is expected to be required to handle the large amount of data and reports that will be gathered and submitted under these proposed regulations. Appendix C presents the assumptions related to the cost of developing and maintaining a data management system.

These costs are summarized in Table 10 and Table 11 below. In Table 10, costs are totaled per Article and additional program cost category; because some costs are one-time while other costs will be incurred annually, program costs are not summed in this table. In Table 11, costs are distributed annually over the first six years of the program. For example, the initial chemical listing process described in Article 2 is assumed to occur in the first and fourth year of the program, and hence those costs have been divided between year 1 and year 4. Likewise, the review of AA reports and initiation of associated regulatory responses is expected to take place in the two years following the publication of the priority product list, and thus those costs are divided among the first two years. Other costs are experienced annually—such as the petition and auditing processes. Table 11 presents assumptions for the years in which each cost will be incurred.[15]

As shown, annual costs are estimated to range from about $9.3 to $34.4 million under the scope of the May 2012 Informal Draft Regulation. Thus, at the upper end of the range, DTSC's estimate of annual program costs of approximately $10 to $13 million[16] is on the lower bound of the cost estimates made in this assessment, although the scope of the program DTSC estimates implementing for that cost is not currently known. However, the scope might be revealed if DTSC releases an economic analysis with the formal release of the draft regulation. In addition, program costs are expected to increase in the out-years as the number of priority chemicals and products cumulates and decrease slightly because of efficiencies of scale.

The following broad conclusions are drawn from this cost analysis:

- **Annual DTSC implementation costs are estimated to range from about $9 to $27.2 million in the first six years, depending on the assumed scope of the SCP program**. These costs could be even higher if more chemicals or products are reviewed by DTSC, if more industry consortia submit AA Reports for review by DTSC, or if additional regulatory actions are pursued. Conversely these costs would reduce if the scope of the program is narrowed.

[15] This assumes that the list of priority products is revised per the minimum stated requirement of at least once every three years.
[16] See DTSC's 45-day notice issued for the SCPA regulations, Department reference number R-2010-05.

- **Annual costs over time for the program are expected to increase as the cumulative number of priority chemicals and products regulated by DTSC also grows.** DTSC's SCP program will be an ongoing effort to continually assess and regulate additional priority chemicals and products. Thus, DTSC is expected to continue to review and list new chemicals and products, and thus new AA reports will be generated and new regulatory responses will be pursued. As the total number of regulated chemicals and products grows, it is likely that the cumulative burden on DTSC will also trend upward in the out-years beyond the scope of this analysis.

Table 10: Summary of DTSC Implementation Costs by Article

	Program	
	Total FTE	**Total Cost**
FTE costs by Article		
Article 2: Chemical Prioritization Process	145.2	$25,190,000
Article 3: Product Prioritization Process	53.9	$9,350,000
Article 4: Petition Process	14.4	$15,000,000
Article 5: Alternatives Assessments	88.4	$15,320,000
Article 6: Regulatory Responses	14.7	$2,550,000
Article 9: Audits	0.3	$360,000
Article 10: Confidentiality of Information	1.4	$1,440,000
Additional program costs		
General program administration	6.0	$4,860,000
Data management system development and hardware/software*	--	$1,700,000
Data system upkeep and management*	--	$2,400,000

* See Appendix C for estimation of data management system costs.

Table 11: Summary of DTSC Implementation Costs by Year Incurred under this Program

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
FTE costs by Article:						
Article 2: Chemical Prioritization Process	$12,595,000			$12,595,000		
Article 3: Product Prioritization Process	$4,675,000	$4,675,000		$4,675,000	$4,675,000	
Article 4: Petition Process (Annual)		$2,500,000	$2,500,000	$2,500,000	$2,500,000	$2,500,000
Article 5: Alternatives Assessments		$5,106,667	$5,106,667	$5,106,667	$5,106,667	$5,106,667
Article 6: Regulatory Responses				$850,000	$850,000	$850,000
Article 9: Audits (Annual)					$60,000	$60,000
Article 10: Confidentiality of Information	$240,000	$240,000	$240,000	$240,000	$240,000	$240,000
Additional program costs:						
General program administration (Annual)	$810,000	$810,000	$810,000	$810,000	$810,000	$810,000
Data management system development & hardware/software	$850,000	$850,000				
Data system upkeep and management (Annual)		$400,000	$400,000	$400,000	$400,000	$400,000
TOTAL ANNUAL COSTS						
Annual Costs	$19,170,000	$14,581,667	$9,056,667	$27,236,667	$14,641,667	$9,966,667

Appendix A: Assumptions for DTSC Government Wage

Four employee categories of labor (junior staff analyst, associate staff analyst, manager, and senior manager) were used in this cost analysis. Rates were assigned based upon position salaries listed in the 54th edition of the California State Civil Service Pay Scales. It should be noted, however, that a number of other specialists from other professional fields are also likely to be engaged in carrying out some portion of the tasks associated with DTSC's administration of the regulation. For purposes of assessing the costs for this program we have constrained the number of labor categories to the four identified above under the assumption that the range of costs associated with these four categories will be representative of labor costs for other personnel that might be involved with the regulatory process. An overall level of effort was determined for each activity, and a set percentage of that LOE assumed to be performed by each labor category (i.e., 30% by junior staff, 40% by associate staff, 20% by managers, and 10% by senior managers), as shown in Table 12 below.

The average hourly wages were derived from the California pay scales for employees as determined by the Department of Personnel Administration[17] and include a multiplier factor of 2.1 applied for overhead and benefits, as recommended by EPA in Assessment of Compliance Assistance Projects Compliance Information Collection Requests (ICRs). [18] These wages are shown in Table 12.

Table 12. Government Labor Costs Used in the Cost Analysis

Labor Category	Employee Category	Percentage of LOE	Hourly Wage Rate (loaded)	Cost per FTE
Junior Staff Analyst	JY25	30%	$39.54	$82,249
Associate Staff Analyst	JY35	40%	$59.05	$122,828
Manager	BH80	20%	$88.39	$183,849
Senior Manager	BH76	10%	$102.00	$212,154
Weighted Average			**$63.36**	**$131,791**

[17] California State Civil Service Pay Scales - Online Manual 54th Edition. CA Department of Personnel Management. 2010. Available online at: < http://www.dpa.ca.gov/publications/pay-scales/index.htm >.

[18] Information Collection Request for Assessment of Compliance Assistance Projects. EPA. Available online at: <http://www.epa.gov/oecaerth/resources/publications/assistance/measures/generic-icr-186003.pdf>

Appendix B: Estimated Costs Associated with Toxicological Tests for an Individual Chemical

While DTSC is assumed to incur no extramural costs for the generation of toxicity test data, to the extent that such test data is required to make listing determinations, the generation of that data could be costly for responsible entities and/or chemical manufacturers who would be involved in developing the information for DTSC use.

The cost of testing for just a single chemical can be substantial. Although the 1998 EPA study estimated the cost of a basic set of test data at approximately $200,000 per chemical,[19] information from other sources—including from testing laboratories and other studies—suggests that those costs can be significantly higher. Table 13 below summarizes these potential testing costs.

Table 13. Range of Toxicological Test Costs for an Individual Chemical

Test Type	Description/ Comments	Associated Costs *
Mandatory Tests under SB 578 §25432		
Carcinogenicity	Test Protocol: This test requires the review of 40 tissues plus lesions/tumors Animal Testing Burden: Test protocol requires the use of 1000 rodents (2 sexes per species, 2 species, 500 animals per species) Cost Considerations: The low end of the cost range would be highly unlikely. Any result of toxicological significance requires more detailed pathology which will increase the cost. The choice of rat species will affect the cost—Charles River rats are more expensive than Fischer rats because they must be housed individually.	$1.1 million (for a mouse study) to ~$5 million
Reproductive Toxicity	Test Protocol: EPA Protocol 870.3800 • 2-generation rodent reproduction study Animal Testing Burden: • 1800 laboratory rats (parental = 20 males with 20 dams per dose group = 40 * 4 dose groups = 160 rats) • Each rat will litter about 10 pups (800 pups = F1 generation). F1 breeding = 1 male * 1 female per litter = 80 * 10 = 800 pups in the F2 generation.	$700,000 to $1,000,000
Tests That Could Be Required If Determined to be Technically Feasible Under SB 578 §25433		
Developmental Toxicity	Test Protocol: EPA Protocol 870.3700 Animal Testing Burden: • Test protocol requires 2 species of lab animals (rodents and rabbits) • 1600 laboratory animals per substance (20 pregnant dams per dose group, 4 dose groups total * 2 species = 160 dams) • Each rat will litter about 10 pups (800 pups); each rabbit will litter about 8 offspring (640 offspring)	$250,000 to $300,000

[19] The set of testing data assumed here is based on those tests required by the Organization for Economic Cooperation and Development's Screening Information Data Set (OECD/SIDS) program: acute toxicity; chronic toxicity; developmental/reproductive toxicity; mutagenicity; ecotoxicity and environmental fate.

Test Type	Description/ Comments	Associated Costs *
	Cost Considerations: • The rabbit study will be more expensive because they require larger inhalation chambers	
Neurotoxicity	Test Protocol: EPA Protocol 870.6200 (Neurotoxicity screening battery) Animal Testing Burden: • Neurotoxicity screening battery requires 80 – 120 laboratory rats (10-15 per sex per dose group; 3 doses + control group) Test Protocol: EPA Protocol 870.6300 • Developmental neurotoxicity study Animal Testing Burden: • 1300 – 1600 laboratory rats	$700,000 to $1,000,000
Immunotoxicity	Test Protocol: No standard protocol for immunotoxicity testing is in use.	~$86,000
Endocrine Screening	Test Protocol: No standard protocol for endocrine screening is in use. • EDSP Tier I screening assays include: o Uterotrophic (24 rats) o Male pubertal (45 rats) o Hershberger (24 rats) o ER/AR binding o Adult male (60 rats) o Steroidogenesis o Aromatase o Amphibian metamorphosis o Female pubertal (4 rats) o Fish screen Cost Considerations: • Because there is no standard protocol for endocrine screening, it is possible that the costs of these tests could be much higher.	$400,000 to $1,000,000
Respiratory Toxicity	Test Protocol: No standard protocol for respiratory toxicity is in use.	$82,000
Tests More Typically Conducted on Chemicals in Production		
Acute Oral Toxicity	Test Protocol: LD50 test, OPPTS 870.1100 • Test evaluates the dose at which 50% of the test population dies • Clinical observations, body weights, food consumption, clinical pathology, gross pathology, histopathology (30 tissues plus lesions) Animal Testing Burden: • 40 laboratory rats (4 groups, 5 rats per sex per group)	$4,000 to $32,000
Acute Inhalation Toxicity with Histopathology	Test Protocol: • In this test, the highest dose is given to determine how many	$25,000

Test Type	Description/ Comments	Associated Costs *
	animals die. • Tissues are cut, but they are not evaluated.	
90-day Subchronic Oral Toxicity	Test Protocol: OECD 408, OPPTS 870.3100 • Clinical observations, body weights, food consumption, clinical pathology, FOBs, urinalysis, gross pathology, histopathology (40 tissues plus lesions) Animal Testing Burden: • 80 laboratory rats (4 groups, 10 rats per sex per group)	$150,000 to $200,000
2-year Chronic Oral Toxicity	Test Protocol: OECD 452 • Clinical observations, body weights, food consumption, clinical pathology, urinalysis, gross pathology, histopathology (50 tissues plus lesions/tumors) Animal Testing Burden: • 160 laboratory rats (4 groups, 20 rats per sex per group) Cost Considerations: • A 2 year chronic inhalation toxicity study would be twice as expensive as the chronic oral toxicity study because it is time- and labor-intensive to move the animals in and out of the inhalation chamber each day (or 5 out of 7 days per week)	$750,000 to $1 million
Mutagenicity Screen	Test Protocol: This study is done to indicate whether further carcinogenicity testing is needed.	$4,000 to $6,000

* Costs are based on: (a) estimates received from the following testing laboratories— Alberta Research Council, Best American Toxicology Testing Services, IIT Research Institute, and Toxicon Corporation—which were contacted between May 24, 2007 and June 12, 2007; (b) responses from ACC members (May & June, 2007 and July 13, 2012); and (c) estimates from Becker (2007), Crofton (2006), EPA (1997), NIEHS (1997), and Belzer (2009).

References:

Becker, Rick. 2007. Comments on Costs and Animal Welfare Impacts of Toxicity Testing Requirements of SB 578.

Belzer, Richard B. 2009. An Analysis of EPA's Information Collection Request Seeking OMB Approval to Impose Mandatory Tier 1 Assay Testing in Support of the Endocrine Disruptor Screening Program. May 21.

Crofton, Kevin. 2006. Developmental Neurotoxicity Testing: The Challenge. March 13. Available at <http://caat.jhsph.edu/programs/workshops/testsmart/dnt/proceedings/2_Crofton.ppt#274,6,Current Testing Approach versus Reality>.

NIEHS. 1997. Health Agencies, Regulated Industry Agree to Seek New, Faster Standard Animal Test for Cancer-Causing Chemicals. February 27. Available at <http://www.hhs.gov/news/press/1996pres/960227.html>.

U.S. EPA. 1997. Appendix B: Estimating the Testing Costs. Available at <http://yosemite.epa.gov/ee/epa/riafile.nsf/vwAN/TS0000365E-03.pdf/$File/TS0000365E-03.pdf>.

Appendix C: Data Management System Development and Maintenance

DTSC will receive and manage data, notifications, requests, and reports from businesses related to listed chemicals and products from potentially tens of thousands of businesses. It is not clear whether DTSC will accept electronic submissions (e.g., through a Web site), although it is likely that such a system would be an efficient selection. At a minimum, DTSC will need a data management system that can perform basic functions, including tracking receipt of information from industry, maintenance and management of data, and searching and reporting. For example, in order to review the data submissions, DTSC staff may need to query the database to aggregate data by chemical, or to search for all products of a certain type that contain priority chemicals. In developing the system, special provisions for dealing with and protecting confidential business information will need to be developed, as will a an interface for information made publicly available.

Table 14 presents the estimated cost of developing such a data management system. As shown, development costs, including systems development and guidance documentation development, represent the large majority of the cost of a data management system. Hardware and third party software costs are estimated in the range of $100,000 to $300,000 for an electronic submission receiving system alone. A total one-time cost of approximately $800,000 to $1,700,000 is consistent with costs of developing similar systems for State-level EPAs in the past, which have typically ranged from $1 to $10 million, with maintenance costs of up to $5 million annually depending on the evolution of system requirements and the costs to cleanse and manage the data. The annual costs of maintaining the data management system are estimated to range from $100,000 to $300,000, depending on the level of maintenance required. The lower bound estimate includes only base costs to keep the system running and fix bugs; the upper bound estimate would cover adding new functionality and operations activities (such as hosting).[20]

Table 14. Estimated Total One-Time and Annual Cost of Developing a Data Management System

Data Management System Task	Range of Costs
Development, including: Systems analysis and design Systems development (e.g. of electronic reporting forms, user interfaces for electronic data submission, and functionality) Systems testing Guidance documentation development	$700,000 - $1,400,000
Acquiring and setting up hardware and software	$100,000 - $300,000
Total Set-up Costs	**$800,000 - $1,700,000**
Maintenance	$100,000 - $400,000

[20] These costs are also consistent with those estimated by DTSC for the development of a Toxics Information Clearinghouse (TIC), as mandated by Health and Safety Code Section 25256; a feasibility study report estimated approximately $1.1 million in one-time development costs, plus about $400,000 in continuing costs.[20] The TIC would provide a Web-based system for collecting, maintaining, and distributing chemical hazard trait and environmental and toxicological end-point data.

ACC Attachment 5

MICHAEL P. WALLS
VICE PRESIDENT
REGULATORY & TECHNICAL AFFAIRS

October 11, 2012

United States
US – TBT Enquiry Point
Washington, D.C.
Submitted via email to: ncsci@nist.gov

RE: TBT Notification G/TBT/N/USA/727 – Proposed California Department of Toxic Substances Control "Safer Consumer Product Regulation"

Dear Sir or Madam:

The American Chemistry Council (ACC) believes that the California Department of Toxic Substances Control's (DTSC) proposed Safer Consumer Product Regulation, notified to the World Trade Organization's (WTO) Technical Barriers to Trade Committee, August 8, 2012, raises several significant concerns about conformance with WTO obligations and its potential impact on global trade. ACC hopes that these comments will prompt DTSC to reevaluate key elements of the regulatory proposal, maintaining a framework that is protective of human health and the environment while avoiding adverse trade and negative competitive impacts.

ACC is most concerned with the potential trade implications of three elements of the proposed regulation:

- The complexity, scope and likely burden of the draft stand at odds with federal U.S. efforts to reduce regulatory burdens.
- The Priority Product identification, Alternatives Analysis Threshold, and alternatives assessment accreditation and certification may well be inconsistent with Article 2.2 of the Agreement on Technical Barriers to Trade (TBT Agreement).
- The proposed disclosure of trade secrets, for instance chemical identity, may violate Article 39.1 and 39.2 of the Agreement on Trade Related Intellectual Property (TRIPS).

Counter to U.S. Efforts to Reduce Regulatory Burdens and Provide Clarity

The United States is committed to improving regulation and regulatory review, as evidenced by Executive Order (E.O.) 13563, signed by the President, January 18, 2011. E.O. 13563 complements a 1993 E.O. titled, "Regulatory Planning and Review," stating that the U.S. regulatory system must protect public health, welfare, safety, and our environment while promoting economic growth, innovation, competitiveness, and job creation. It also must do the following: promote predictability and reduce uncertainty; identify and use the least burdensome and most innovative tools for achieving regulatory goals; take into account qualitative and

quantitative benefits and costs; and, ensure regulations are accessible, consistent and written in an understandable manner. The proposed California regulation fails to take into consideration or address a number of the aforementioned elements.

The Economic and Fiscal Impact Statement completed by DTSC is indicative of the lack of certainty provided by the proposed regulation.[1] Although the form notes that this regulation will impact businesses and/or employees, small businesses, jobs or occupations and California competitiveness, it does not offer any quantitative figures related to these impacts. For example, the total number of affected businesses and statewide dollar costs are listed as "unknown."

A second example is California DTSC's proposed unique process to establish the "Alternatives Analysis Threshold" level, or *de minimis* level. The Alternatives Analysis Threshold neither follows the precedent set by the Globally Harmonized System (GHS) for Classification and Labeling, nor the precedent set by the European Union's REACH program. A *de minimis* threshold of 0.1% is essential to identifying and prioritizing the products containing chemicals of legitimate concern, that have potentially harmful exposures. From a technical perspective, 0.1% is the most practical threshold level that will avoid unnecessary assessments and reformulations based on the mere presence of trace amounts of a chemical of concern. In addition to GHS classification and REACH, a number of other standards and regulatory programs defer to the internationally accepted level of 0.1% (e.g., the Consumer Product Safety Commission, and Europe's Classification, Labeling and Packing (CLP) Regulation), thus millions of dollars are invested in compliance at this level on a global scale. This may be in conflict with Articles 2.6 and 2.7 of the TBT Agreement.

Proposed Regulation Will Likely Create Unnecessary Obstacles to International Trade

DTSC's regulatory proposal could affect nearly every product sold in the State of California, with subsequent impacts on the U.S. market as well as abroad. The scope of the program, largely dictated by the California Health and Safety Code's definition of "consumer product"[2] is broad. The proposed regulation establishes unique criteria for the identification and prioritization of "Chemicals of Concern" and "Priority Products". It also establishes a unique set of requirements for conducting an alternatives assessment, as well as who may perform such an assessment. Particular aspects of the proposed regulation, such as the previously mentioned Alternatives Analysis Threshold, may be more trade restrictive than necessary to fulfill the objective of the regulation, potentially in violation of Article 2.2 of the WTO TBT Agreement.

Second, as constructed, the proposed regulation will likely create less favorable conditions for suppliers outside of the U.S. during implementation. The Alternatives Assessment process, including the program to establish accredited bodies and subsequently, certified

[1] State of California Department of Finance "Economic and Fiscal Impact Statement (Regulations and Orders)," http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/SCP-399-7-17-2012.pdf.
[2] California's Health and Safety Code §25251 defines "consumer product" as, "a product or part of the product that is used, brought, or leased for use by a person for any purposes. 'Consumer product' does not include any of the following: 1) A dangerous drug or dangerous device…; 2) Dental restorative materials…; 3) A medical device…; 4) A food…; 5) Packaging associated with 1), 2), or 3); and, 6) A pesticide."

assessors may also be inconsistent with Articles 2.1 and 7.1 (though its reference to Article 5.1) of the TBT Agreement. The accreditation and certification aspect of the alternatives assessment provisions appear to favor the specific capabilities of the U.S. university system. Alternatives assessment, generally speaking, may be accomplished using a number of different methodologies. There is not one correct way to complete such an assessment; and, not all cases of alternatives assessment require the same considerations or level of expertise in every disciple. In practice various industries and companies conduct alternatives assessments somewhat differently, according to the product segment and task at hand.

Protection of Confidential Business Information

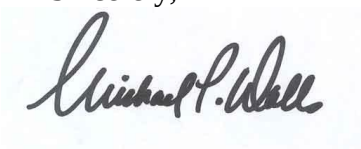
The proposed regulation requires an unprecedented level of information about products, chemicals, and manufacturers' business plans and operations to be made publicly available. ACC is particularly concerned that DTSC will not have the staff or physical resources to properly process, adjudicate, manage and store the volume of information that will be reported under the proposal. Much like U.S. federal and state laws protecting confidential business information and trade secrets, DTSC must also be mindful of Article 39.1 and 39.2 of the WTO TRIPS Agreement.

Article 39.1 and 39.2 of the WTO TRIPS Agreement require WTO members to protect undisclosed information, and to make it possible for natural and legal persons to prevent trade secrets from being disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practices. The information that must be protected is information that is secret, in the sense that it is not generally known within circles that normally deal with that kind of information; that has commercial value because it is secret; and that has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret.

* * * * *

As drafted, the DTSC proposal establishes several unnecessary burdens to international trade that may violate the Technical Barriers to Trade Agreement. ACC believes that additional clarification of DTSC's intended scope and approach, and modification of the provisions noted above, will result in a regulatory system that more fully conforms to WTO practice and discipline while assuring a high level of health and environmental protection. If ACC may provide any additional information, please contact me.

Sincerely,



Michael P. Walls
Vice President
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