ACC COMMENTS ON THE PROPOSED REGULATIONS – POST-HEARING
CHANGES SAFER CONSUMER PRODUCTS (R-2011-02) January 29, 2013

The exemption for bulk chemicals should be restored.
ACC urges DTSC to exempt both bulk chemicals and products manufactured in or transported through California solely for use outside of California from the Safer Consumer Products Regulation. The goal and intent 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 Products Regulation therefore should be the “Chemicals of Concern” (COC) in “Priority Products,” not on bulk chemical manufacturing and transportation. It is unclear why DTSC has included bulk chemicals within the scope of the regulation. As a practical matter, neither manufacturers nor DTSC have the capacity to include the entire universe of manufacturing materials (may be referred to as a “chemical” or a “product”) in a regulation aimed at final consumer products. As noted in our comments dated October 11, 2012, the bulk chemical exemption should be restored.

Furthermore, ACC requests DTSC clarify why the applicability of the proposed rule has been revised to address products placed into the stream of commerce in California solely for the manufacture of one or more of the products exempted from the definition of “consumer product” specified in Health and Safety Code section 25251, and any consumer products manufactured or stored in or transported through California solely for use outside the State. Currently, these factors are merely “adverse impact and exposure factors” considered in the product-chemical combination prioritization process. Federal statutes, such as the Occupational Safety and Health Act, the Hazardous Materials Transportation Act, the Federal Hazardous Substances Act, and the Controlled Substances Act, already regulate the manufacture and transport of chemical products.

The definition of “import” requires further clarity.
The proposed definition of “import” is unclear. The proposal states that “‘import’ does not include ordering a product manufactured outside of the United States if the product is ordered from a person located in the United States.”¹ This particular statement appears to contradict the intended scope of the provision. ACC believes DTSC may be referring to an individual placing a personal order for a product manufactured outside of the U.S., but not for commercial resale. ACC requests clarification of “import” as defined in the proposed regulations.

The revised definition of “reliable information” should include a weight-of-evidence approach.
Although marginally improved from previous definitions of “reliable information,” the latest definition does not guarantee reliance on quality science through a weight-of-evidence (WoE) approach. As noted in our comments dated October 11, 2012, without a WoE 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.² WoE means a

¹ §69501.1(a)(38).
² OEHHA Green Chemistry Hazard Traits for California’s Toxics Information Clearinghouse (October 7, 2011), §64206.6(b).
systematic evaluation that assesses the adequacy, strength, and consistency of the scientific information utilized for identifying Candidate Chemicals and the process for prioritizing consumer products containing Chemicals of Concern. WoE also facilitates identifying potential alternatives to Priority Products in order to determine how best to limit exposures to, or the level of adverse impacts posed by, the Chemical(s) of Concern in the Priority Product.

In carrying out a WoE evaluation, the Department should determine whether a consistent and biologically plausible scientific understanding of significant adverse effects emerges from a comprehensive evaluation of relevant scientific studies, including null findings, taking into account the following:

- The scientific quality of each study and the relevance, reliability, sensitivity, and specificity of each test method;
- Whether study results demonstrate similar adverse effects across species, strains, and routes of exposures;
- Clear evidence of a dose-response relationship;
- A scientifically plausible relationship between mode or mechanism of action, the adverse effect of concern, and data on absorption, distribution, metabolism and excretion;
- Comparison to toxicity exhibited by structurally related compounds using a scientifically valid method; and,
- The extent to which scientific evidence does, or does not, support a causal link between specific exposure to the chemical and evidence of the adverse effect of concern in humans or in other relevant species.

ACC urges DTSC to include a WoE approach in the regulation, as it is critical to agency decision making, particularly with regard to prioritizing Candidate Chemicals and products. It would reinforce DTSC’s commitment to science-based decision making.

**DTSC should not rely upon European lists still under development as the basis of candidate chemical listing.**

The July 27, 2012, proposed rule offered 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*, as a basis for what was then termed the “Chemicals of Concern” list. Given that this was intended as a preliminary list that was subsequently modified, DTSC correctly removed that resource as a listing trigger in the present proposal.

DTSC has replaced that trigger, however, with a reference to “[c]hemicals included as endocrine disruptors identified in the candidate list of Substances of Very High Concern in accordance with Article 59 of Regulation 1907/2006.”³ As DTSC is aware, this is a list that has yet to be populated by European authorities. An initial list could be released in 2014, and is expected to be modified over time as new information and analysis becomes available.

³ §69502.2(a)(1)(C).
As such, the use of this list as a trigger for Candidate Chemical listing in California represents a “dynamic incorporation,” a practice that raises due process and non-delegation concerns. Professor Dorf of Cornell calls dynamic incorporation “a prima facie threat to the democracy of the incorporating polity because it takes decisions out of the hands of the people's representatives in that polity and delegates them to persons and bodies that are accountable only to a different polity, if at all.”

California courts have long regarded dynamic incorporation as constitutionally flawed. As the court in Brock v. Superior Court noted:

> It is, of course, perfectly valid to adopt existing statutes, rules or regulations of Congress or another state, by reference; but the attempt to make future regulations of another jurisdiction part of the state law is generally held to be an unconstitutional delegation of legislative power.

For this reason, the California Court of Appeals has observed that “[w]hile existing statutes may be incorporated by reference, prospective incorporation has never been approved by a California court.”

**DTSC’s approach to regulating intentionally added chemicals and contaminants should be revised.**

The proposed rule lacks a threshold for intentionally added COCs, based on the risk posed by the COC in the product. Manufacturers must measure the contaminants in the Priority Product, down to the Practical Quantitation Limit (PQL). The “practical quantitation limit” is defined as the “lowest concentration of a chemical that can be reliably measured within specified limits of precision and accuracy using routine laboratory operating procedures.” Essentially, DTSC is stating that intentionally added chemicals are subject to alternatives assessment if they are present in the priority product at any concentration, whereas contaminants are subject to reporting if they can be detected in the product. This is a meaningless distinction and effectively treats intentionally added chemicals identical to contaminants.

PQL is an analytical term. For any material, PQL is subject to change with instrumental technology and methods development. It is in no way related to the potential harm that could be caused by chemicals present in products at such low levels as to be barely observable, and has no bearing on whether these barely detectable materials could migrate from the product and if so whether such migration results in any detectable exposure for users of the product.

---


7 §69501.1(a)(52).
A better approach would be to set numerical thresholds for intentionally added chemicals that are harmonized with those applied by federal and international agencies. As noted previously, in our comments dated October 11, 2012, harmonization with numerical thresholds set by federal and international bodies would be consistent with the enacting statute.\(^8\) 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 risk-based de minimis threshold of 1% for hazardous chemicals, and 0.1% for carcinogens, mutagens, and reproductive toxins. Provided the manufacturer has done its due diligence to remove contaminants from the product, contaminants should be exempt from reporting.

Further, DTSC should treat intentionally added chemicals and contaminants in a manner that incentivizes efforts to limit them. Washington State has adopted such an approach in implementing its *Children’s Safe Product Act*, Chapter (70.240 RCW). Washington allows product manufacturers the option of not reporting contaminants if they have in place a “manufacturing program to minimize contaminants in their products” and “use due diligence to ensure the effectiveness of the program.”\(^9\) Washington encourages manufacturers to use process improvements, contract specifications, testing and auditing to reduce the presence of contaminants in final products, while recognizing that “intentionally added chemicals…offer the best opportunity for substitution with a safer alternative and should be where we focus most of our attention.”\(^10\)

**DTSC’s approach to prioritizing product-chemical combinations is overly subjective and is missing key scientific elements.**

Prioritization is central to any benefits that will be derived from the regulation. DTSC must employ a rigorous scientific process for selecting product/COC combinations. Despite suggestions made by industry groups for a more quantitative prioritization approach that draws on sound scientific principles such as Canada’s program (where 500 high priority chemicals have already been assessed and risk management action taken where appropriate), DTSC instead has proposed a non-quantitative product-chemical prioritization process. This so-called “narrative standard,” in ACC’s view, is not scientifically defensible for identifying high priorities, and its use may not make meaningful improvements to public health and the environment in California.

In addition, ACC recommends that DTSC add a critical “route of exposure” descriptor to §69503.3(b)(3)E. Currently the provision mentions only “frequency, extent, level and duration.” The route of exposure is a critical consideration in determining the potential for adverse impacts.

Unfortunately, the proposed rule has weakened the prioritization process to the point where virtually any ingredient in any product could arguably be selected as the Priority Product.

---


The use of the term “potential” could weaken DTSC’s focus.
The term “potential,” which had been largely dropped in the July 2012 proposal (e.g. potential adverse effects, potential exposures, etc.), has been returned to virtually every definition, prioritization criterion and consideration. This could overwhelm DTSC with all manner of hypothetical scenarios. Although, this change is somewhat mitigated by the addition of a definition for potential ("…that the phenomenon described is reasonably foreseeable based on reliable information"). DTSC should focus on expected and probable health and environmental concerns, not every imaginable possibility. Furthermore, ACC recommends that the definition of the term “potential” include the concept of likelihood, e.g. “…that the phenomenon described is likely and reasonably foreseeable based on reliable information.”

Key Principles must reflect the fact that presence does not equal harm.
A vital phrase has been eliminated from the Key Principles. This phrase, “…in quantities that would contribute to or cause adverse…impacts,” demonstrates the potential for exposure to the chemical in the product to occur at a magnitude, frequency, and duration that raises a concern for potential health and/or environmental effects to arise. This is a critically important part of the Principles and ACC recommends that it be reinstated.

The exposure factors in §69503.3(b) are broad, yet relevant to the prioritization process. The focus of the exposure criteria, however, often seems to be on “presence,” “contact” and “occurrence,” which do not equate to exposure. This suggests an entirely qualitative evaluation, which could result in opinions and perceptions driving the process. Indeed, this approach suggests the potential for arbitrary decisions rather than a deliberative scientific effort to identify high priorities with real and significant threats to human health and the environment. Qualitative information, while helpful in indicating existence, occurrence, contact or presence, cannot make up the sole factors in determining whether a situation creates an exposure with the potential for adverse impacts. Presence does not equate to harm or to risk, and quantitative information demonstrating the potential for exposures to occur at levels of toxicological concern must be a primary driving factor in priority setting decisions.

ACC recommends that the underlined phrase be reinstated in the Principles, §69503.2(a)(2), “[t]here is significant ability for public and/or aquatic, avian or terrestrial animal or plant organisms to be exposed to the Chemical(s) of Concern in the product in quantities that would contribute to or cause adverse public health or environmental impacts.”

ACC supports use of an APA rulemaking process to update the Priority Products List.
ACC supports the provision that updates and revises the Priority Products List through a rulemaking process pursuant to the Administrative Procedure Act. We are hopeful the rulemaking process will permit all stakeholders to provide a range of data and information to DTSC, which will enable DTSC to make objective and economically sound Priority Product decisions. ACC is concerned that the absence of quantitative, objective decision-making criteria

11 §69501.1(a)(51)(A).

for prioritization, including how to assess economic impacts, could result in further uncertainty and additional burdens on industry during the rulemaking process.

**The proposed regulation should allow manufacturers the option of demonstrating the safety of a Priority Product.**

ACC is concerned that the proposed regulation relies on chemical elimination rather than safe use (e.g., see discussion above on the PQL provision and in proposed “Removal/Replacement Notification in Lieu of Alternatives Analysis”). This bias will in turn promote unwarranted product de-selection by the value chain. As noted in our comments dated October 11, 2012, we firmly believe the approach described in the proposed regulation stands in sharp contrast to the statutory requirement that DTSC’s regulations must “…determine how best to limit exposure or to reduce the level of hazard posed by a chemical of concern…”

Throughout the proposed rule, DTSC should recognize the importance and benefit of incremental improvements as the program commences. Based on a manufacturer’s demonstration of safe use for particular chemicals in a particular product, limiting exposure or reducing the level of hazard posed should be sufficient for compliance.

The proposed regulation, however, is not clear as to when, if at all, manufacturers may demonstrate the safety of a product/COC combination. Furthermore, the rule does not allow manufacturers to make a “safety case,” and instead compels the Alternatives Analysis (AA) process. ACC strongly recommends that DTSC revise the proposed rule to enable manufacturers to demonstrate the safety of specific product/chemical combinations. The mere presence of an identified Candidate Chemical or COC should not be presumed to indicate potential harm. If manufacturers can demonstrate the safety of their product, the product should not be required to complete the AA process.

**DTSC must change its proposed regulation to protect confidential chemical identities consistent with California trade secret law.**

The proposed regulation fails to adequately protect confidential chemical identity, which is critical to companies’ ability to innovate and develop new and improved products and formulations – including “greener” ones. Although the revised proposal attempts to expand protection to confidential chemical identity by allowing trade secret protection when a patent application is pending for a chemical or its use in a product, the proposal actually confuses two distinct types of intellectual property protections (patents and trade secrets), and threatens to erode existing federal and California statutory trade secret law protections.

Broadly speaking, intellectual property rights relate to legal protection for ideas. A copyright protects works of authorship (not relevant to a chemical identity). A trademark distinguishes the goods of one party from those of others, and a service mark does that for services (not relevant to a chemical identity). A patent is a limited duration property right relating to an invention in exchange for public disclosure of the invention (potentially relevant to a chemical identity). These intellectual property protections are all federal rights.

---

13 California Health and Safety Code Section 25253.
A trade secret is a formula, pattern, or device which is used in business and which provides an opportunity to obtain an advantage over competitors who do not know or use it. A chemical identity may be a trade secret. A key aspect is that the subject must remain a secret, and must not be readily ascertainable. If it is disclosed publicly, it is lost. State law generally governs trade secrets.

Under the California Uniform Trade Secrets Act (CUTSA), modeled after the Uniform Trade Secrets Act (UTSA), a trade secret is information, including a formula, pattern, compilation, program, device, method, technique or process that:

1. Derives independent economic value, actual or potential, from not being generally known to the public or to other persons who can obtain economic value from its disclosure or use; and
2. Is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.\(^{14}\)

Patents are inadequate to protect confidential chemical identities. A trade secret chemical identity may not qualify for a patent. To be patentable, an invention must meet strict requirements for novelty and utility, plus it cannot be obvious to relevant experts. A chemical identity or its use in a mixture may not meet those requirements. To be patented, an invention must be an advance upon the prior art. Novelty and non-obviousness are measured against the prior art. For a trade secret, however, the prior art is irrelevant. A trade secret need only provide economic value from not being generally known to or readily ascertainable by competitors. For example, the identity of a new chemical may be a logical development from previous chemicals that were known to experts, and therefore not patentable. It may be a trade secret, however, if it provides an actual or potential economic advantage over others.

A patent freezes technology, but a trade secret builds on it. A patent covers technology as it exists at the time the patent application is filed. Subsequent incremental improvements are not covered by the patent. Even if a chemical identity or its presence in a formula for a mixture is covered by a patent, improvements to the chemical structure or formula through additional research and development may qualify as trade secrets.

A patent may not provide adequate protection because it is difficult to enforce. Both patents and trade secrets seek to prevent competitors from using the information (at least without authorization). A trade secret does this by keeping the information from competitors through secrecy. A patent does this by disclosing the information to competitors but giving a right to sue them for unauthorized use.

A patent may not protect against foreign competitors. A patent is good only in the country for which it is granted. A U.S. patent, for example, would not prevent foreign competitors from using the patented information to their own advantage.

Requiring disclosure of trade secret product formulations without imposing an affirmative obligation on the receiving party not to disclose the trade secret to any third party automatically triggers the loss of trade secret protection. The only way trade secret information can be disclosed without forfeiting its trade secret status and its competitive economic advantage is under a confidentiality agreement or to a government agency under a statute guaranteeing confidentiality. Absent such a requirement, DTSC’s proposed disclosure requirements would risk valuable trade secrets to foreign and domestic competitors.

ACC strongly recommends that DTSC to conform its proposed regulations to the CUTSA and protect confidential chemical identities from disclosure as trade secrets.

DTSC should resolve other issues raised in ACC’s October 11, 2012, comments but not addressed in detail here.

ACC is also concerned about a number of provisions that were not addressed in the post-hearing changes proposed rule, for which we commented on in our October 11, 2012, submission. The following points summarize key issues that have yet to be resolved:

- **Products otherwise regulated by federal law should be excluded.**
  Two areas of the proposed regulation appear to duplicate other regulatory programs and further reinforce the inconsistency with the enacting statute. Section 69501 does not exempt food contact materials from the scope of the regulation, and thus duplicates the Federal Food, Drug and Cosmetic Act. 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. At a minimum, DTSC should explain how the inclusion of workers as a potentially sensitive subpopulation does not duplicate CalOSHA’s authority.

- **DTSC should clarify its authority to require information generation.**
  ACC believes the Department should follow the three-step sequential, tiered process for collecting information set forth in §69501.4(a)(1)(A)-(D). 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)(A), 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)(1)(D) beyond the scope of the cited authorizing statute.

- **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. 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.

- **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. The success of DTSC’s regulation depends in large part on the degree to which the compliance and decision making processes are transparent. DTSC should respond to any and all substantive public comments.

- **DTSC should have provided a revised Initial Statement of Reasons (ISOR) with the current proposed rule.**
  DTSC has undertaken an action that appears to be contrary to the spirit and perhaps letter of California administrative procedure law. In order for the population affected by the proposed regulatory action to be best informed and therefore able to “be heard on the merits” in comments on regulations, the proposed regulations are supposed to be accompanied by an explanatory document, the ISOR. Without understanding the rhyme and reason behind all aspects of the proposed regulation, it would be difficult for the affected public to provide informed comments to be considered by the agency. DTSC did not heed the request in ACC’s comments on the revision of the ISOR, dated January 22, 2013, asking that “no regulatory proposal for Safer Consumer Product Alternatives be presented for comment and review without a final ISOR upon which all affected entities can comment in tandem.”

---

15 §69503.3(a)(1)(B)-(C).

16 See, e.g., §69502.3(d).