ACC COMMENTS ON THE ADDITIONAL POST-HEARING CHANGES TO THE SAFER CONSUMER PRODUCTS REGULATION APRIL 2013

A. The revisions to the definitions of “chemical” and “reliable information” require further clarity.

ACC questions the elaboration of the definition of “molecular identity” in the revised proposed regulation. Would any variation in the properties listed in the definition give rise to a new molecular identity? For example, if mean particle density were to vary among batches of the same substance, would DTSC treat each batch as if it had a new molecular identity? ACC notes that it is well understood that many, if not most, of the characteristics listed in the new definition are strongly influenced by environmental conditions and may change in dynamic ways depending on ambient conditions. As a simple example, many of the listed characteristics will be irrelevant once a substance is dissolved. How will DTSC consider this dynamic in identification of molecular identity? ACC cautions that the inclusion of such factors creates an obligation on DTSC’s part to develop guidance that will help responsible entities understand DTSC’s thinking about which properties are relevant to which states of matter under what conditions for the purposes of making hazard and exposure determinations. Finally, ACC questions the scientific rationale for the elaboration of factors. It is our understanding that the phrase “physicochemical properties and structure” would cover everything.

Additionally, it is unclear why the definition of “reliable information,” which had been marginally improved, has since been edited to eliminate references to independent review and independent confirmation or replication. We are left to conclude that DTSC disagrees with the notion that reproducibility is a cornerstone of the scientific method and will instead base its decisions on studies that though attempted to be, cannot be reproduced. A sound definition of “reliable information” that includes independent review and independent confirmation or replication would enhance the scientific credibility of the complex regulatory proposal. ACC encourages DTSC to reinstate the previous language, adding a provision for weight-of-the-evidence assessment as part of the standard protocol.

B. DTSC should focus its efforts only on chemicals and products subject to the requirements of the regulation.

DTSC should focus its efforts on chemicals in consumer products that have the highest hazard and exposure to Californians. Similarly, the Department should also concentrate its efforts on those chemicals and products that are explicitly subject to the proposed regulation. It is questionable whether DTSC currently has authority under Health and Safety Code Sections 25252-25255, and 25257, to require manufacturers, importers, assemblers, and retailers “of any product” to provide information regardless of whether these chemicals or products are subject to the regulation.\(^1\) DTSC must focus the scope of the regulation on chemicals and products that are subject to the proposed rule.

\(^1\) Proposed revised, post-hearing changes Safer Consumer Products Regulation, §69501.4(a)(2).
C. DTSC should correctly characterize chemical lists and should not rely upon European lists still under development as the basis of candidate chemical listing.

In revisions to the citations for the “Candidate Chemical” list sources in Section 69502.2(a)(1), items (B), (C), (G) and (I) are cited as being classified by or included as Substances of Very High Concern (SVHC) candidates for REACH “by the European Commission.” While these processes are conducted under European Union laws, both classification and SVHC approaches are conducted by the European Chemicals Agency (ECHA), which works together with Member States, but has ultimate responsibility for both regulations. The proper citation would be “…by the European Chemicals Agency.” In addition, the revision to (C) indicates that there are “Category 1” endocrine disruptors on the SVHC Candidate list. The SVHC process has no “Category” designation, and therefore “Category 1” should be deleted. The official REACH rationale for these SVHC listings is, “[e]quivalent level of concern having probable serious effects to human health or the environment under Article 57(f).” There are presently 16 chemicals and groups that are candidates under this rationale, some but not all of which are based on endocrine disruption issues. Because the ECHA candidate listing and designations are subject to authorization decisions, which could change their designations, DTSC should not rely on these in developing their own Candidate Chemical list.

D. The distinction between intentionally added chemicals and contaminants is appropriate, but will likely be inefficient in practice.

ACC is encouraged that DTSC differentiates between intentionally added chemicals and contaminants, proposing to allow manufacturers to have a dialogue with the Department regarding appropriate “Alternatives Analysis Thresholds” for intentionally added chemicals. However, contaminants continue to be subject to the alternatives assessment (AA) process. As part of the regulatory process, manufacturers would be required to 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.”

The 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. To keep from indefinitely chasing molecules of contaminants, ACC suggests that DTSC treat intentionally added chemicals and contaminants in a manner that incentivizes efforts to limit them throughout

2 Article 57(f) of Regulation (EC) No 1907/2006.
3 §69501.1(a)(52).
the manufacturing process. DTSC should strike the proposed requirement to measure contaminants down to the PQL. Instead, DTSC could recognize manufacturing due diligence to mitigate contaminants in the final consumer product. 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 demonstrate that they execute a program to minimize contaminants in their products.

**E. Public review and comment on Final AA Reports, coupled with DTSC’s review is a more practical process.**

ACC supports the change made regarding public review and comment of AA reports. It is preferable for the public to provide comments on the Final AA Report, rather than during the middle of the process, and, it is appropriate for DTSC to collect, review, respond to comments at that time, and to propose an “AA Addendum” if necessary. The comment review process should be more consistent when handled by the Department, rather than each manufacturer posting, collecting, reviewing, and responding to public comments directly.

**F. The proposed regulation to protect confidential chemical identities is inconsistent with California trade secret law and should be changed.**

The proposed revised 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” or “safer” substances. 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.

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.\(^4\)

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 granting the patent
holder right to sue 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 via a
confidentiality agreement or submission to a government agency pursuant to a statute that

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guarantees confidentiality. Absent such a requirement, DTSC’s proposed disclosure requirements would expose valuable trade secrets to foreign and domestic competitors, causing significant economic harm.

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