



Styrene Information and Research Center (SIRC)

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RE: Pre-Regulatory Draft – Green Chemistry Hazard Traits, Endpoints, and Other Relevant Data

Dear Ms. Kammerer:

The Styrene Information & Research Center¹ (SIRC) appreciates that the California Environmental Protection Agency's (EPA's) Office of Environmental Health Hazard Assessment (OEHHA) has provided an informal opportunity for interested parties to offer comments on the draft Green Chemistry Hazard Traits, Endpoints, and Other Relevant Data document (henceforth Draft).

They styrene and styrenic resins manufactured by SIRC member companies are used to produce a myriad of products that contribute to the health, safety, and well-being of California's citizens. Our industry has a firm and long-standing commitment to the protection of our employees, community members, and customers, and SIRC has been committed to the principles of sound science during its 23-year mission to expand the body of data on styrene health and environmental effects.

SIRC is supportive of the overarching intent of California's Green Chemistry Initiative (GCI), which envisions a rational, comprehensive system to identify, prioritize and

¹ The Styrene Information and Research Center's (SIRC's) mission is to evaluate existing data on potential health effects of styrene, and develop additional data where it is needed. SIRC has gained recognition as a reliable source of information on styrene and helping ensure that regulatory decisions are based on sound science. For more information, visit <http://www.styrene.org>.

address threats to public welfare and encourage reduced risk throughout product and component life cycles. Therefore, we encourage the development of a fair and balanced approach to identifying chemicals of genuine health effect concern for potential evaluation under the GCI. We believe a GCI grounded by a thoughtful scientific approach can provide the benefit of increased protection to the citizens of California, by identifying alternatives to chemicals, or products, where there is clear evidence of potential health concerns. We respectfully submit the following comments for OEHHA's consideration relative to the Office's effort to provide guidance on how to "evaluate and specify the hazard traits and environmental and toxicological end-points and any other relevant data that are to be included" in the GCI.

General Observations

The Draft effectively identifies *all* substances in our natural and manufactured environment as potential hazards, but does not provide a mechanism for distinguishing significant hazards from trivial or minor hazards. Thus, if adopted as drafted, the rules will not support rational prioritization and action.

A thorough reading of both SB 509 and AB 1879 indicates there was no directive that OEHHA should have prepared a document of such inclusive scope – nor, fundamentally, was OEHHA given statutory authority to *classify* chemicals. In assuming this authority, however, OEHHA has drafted a supportive component of the GCI that suggests *all* chemical substances in the State may be phased out, which certainly is not the intent of the GCI.

In the current Draft, endpoints of concern are characterized so broadly and conflictingly as to provide no threshold for identifying substances as valid hazard concerns. Classifications between various authoritative bodies are not consistent; in some cases, OEHHA has cited one authoritative body and ignored another when defining criteria. Treatment of all the endpoints ultimately is the same – they simply are *so qualitative that they encompass nearly all chemicals*. Oxygen, sand, and water would qualify for the GCI as much as substances universally acknowledged as having true health impacts. As written, the Draft offers no indication of how to prioritize health effect endpoint concerns that potentially will include nearly everything to which a citizen of California is exposed.

Specific Concerns

OEHHA Lacks the Authority to Classify Chemicals: OEHHA proposes in its draft regulation to classify all chemicals as Class One or Class Two chemicals. OEHHA is essentially combining complex classifications from scientific bodies into two categories. That proposal results in concealing the nuances of the other classification systems and results in providing less, not more, data. For example, the proposal takes three significantly different classifications by IARC and reduces it to one simplistic, overstatement.

More significantly, however, than the technical flaws in the classification proposal is the

fact that *nothing in the statute authorizes OEHHA to classify chemicals*. OEHHA's authority is provided by Health and Safety Code section 25256.1. That section provides that "On or before January 1, 2011, the office shall evaluate and specify the hazard traits and environmental and toxicological end-points and any other relevant data that are to be included in the clearinghouse." Nothing in that language contemplates condensing scientific bodies' classification systems into two very general categories. Accordingly, *we urge OEHHA to strike the proposed classification language in its entirety from the next regulatory iteration*.

Limitations of OEHHA's Definition of Adverse Effect: OEHHA states that "adverse effect" means a biochemical change, functional impairment, or pathologic lesion that negatively affects the performance of the whole organism, or reduces an organism's ability to respond to an additional environmental challenge. The definition is ambiguous enough to be both overbroad and under-protective. At one extreme, the definition could be interpreted to mean that any effect is adverse, as it may reduce the ability to respond to other effects. At the other extreme, one could argue that the loss of a finger or hand does not affect the performance of the whole organism; man and other animals clearly do more than survive environmental challenges while lacking normal physiological characteristics. There is a growing body of scientific literature that distinguishes between exposures triggering adaptive effects or sub-clinical changes, and those exposures that lead to a pathological result. OEHHA would be well served in considering such an approach.

OEHHA Has Deemed Itself an Authoritative Body: The Draft defines OEHHA itself as an "authoritative body." Thus, any decisions they have made cannot be challenged because they are "authoritative."

The Draft Lacks Definition of the Studies Necessary to Characterize the Endpoints: Noticeably missing from the Draft is any direction as to the prescribed studies which would be considered in order to characterize the various endpoint traits. For many of the endpoints there presently are not standard guidelines or validated protocols, so *any* data collected presumably could be considered. This will promote the collection and use of data that generally do not follow Good Laboratory Practices (GLP) or standard protocols. Presumably, OEHHA will need to specify what tests/methods are required to assess all of these endpoints; this will be critical to the GCI program. These parameters need to be explicit regarding the field of allowed data, or the information content will be inconsistent and muddled.

Further, OEHHA defines "well conducted studies" as any studies published in the open literature or submitted to a local, state, national or international government agency, using methods and analyses, which are scientifically valid according to generally accepted principles. This implies that *anything* published is well conducted, which categorically is not true. The review and acceptance qualifications of scientific journals vary tremendously; what might meet minimal acceptance standards to one journal may be considered poorly conducted to another. Likewise, it cannot be assumed that *anything* submitted to an agency is well conducted simply on the merit of its receipt by an agency.

One reference point in reconsidering this definition is Klimisch HJ, Andreae E and Tillmann U (1997). *A systematic approach for evaluating the quality of experimental and ecotoxicological data*. Reg.Tox. and Pharm. 25:1-5, which is recognized in the European Union as a starting point in the assessment of scientific studies under REACH.

Lack of Definition on How Differing Findings Will be Assessed: It also is unclear how substances with different findings on different endpoints will be evaluated, in order to determine levels of green. The Draft should include some specification in this area.

Limitations of OEHHA's Approach to Mechanistic Similarity: OEHHA defines "mechanistic similarity" as how a chemical substance acts on a biological system in a manner similar to other chemicals that induce toxicological or environmental effects associated with a specific hazard trait. Although OEHHA uses the phrase "*acts ... in a manner similar,*" historical precedent indicates OEHHA's usual definition and approach to mechanistic similarity is that it need only "*look similar.*" We support a definition of mechanistic similarity that requires *evidence* of similar biochemical or mechanistic action as a criteria, rather than mere structural similarity.

Characterization of Specific Hazard Traits: The characterizing of toxicological endpoints as "hazard traits" makes them *qualitative* endpoints, but all toxicologists know that "the dose makes the poison" – i.e. toxicology is *quantitative*, not qualitative. Sections of the Draft describe a number of endpoints as "present or absent." Small amounts of a chemical may cause none of these endpoint effects, while extremely large doses (orders of magnitude greater than humans can ever be exposed to) may cause several effects. Oxygen, for example, should be classified as at least a Class Two carcinogen under these guidelines, as it causes very large numbers of DNA adducts in all tissues.

Definition of Carcinogen Endpoint Will Cover Virtually All Chemicals: OEHHA's definition in the Draft erroneously assumes carcinogenicity is a *universal trait* – i.e. if there is increased neoplasia in *any* organism, it is carcinogenic. It is unclear how "other relevant data" figures into this classification – can other data rule chemicals *out* as a human carcinogen, or only rule additional chemicals *in*? If applied loosely, almost *every chemical has some effect on one or more of the areas mentioned*. Again, for purposes of prioritization, substances that are clearly human carcinogens should be distinguished from those where human relevance is less certain.

Definition of Cardiovascular Endpoint Will Cover Virtually All Chemicals: Likewise, OEHHA's broad characterization of cardiovascular effects means that – at some dose – almost *every chemical will affect one or more of the endpoints listed*.

Definition of Developmental Endpoint Will Cover Virtually All Chemicals: It is well established that maternal toxicity causes developmental effects. OEHHA ignores that fact in the Draft. Again, the Draft will make it possible to find a reason to *identify almost any chemical as having a "developmental" endpoint under this definition*.

Definition of Endocrine Endpoint Will Cover Virtually All Chemicals: Yet again, OEHHA's Draft offers the possibility that *almost every chemical can be classified as having "endocrine" properties*, based on the Draft's criteria.

Definition of Epigenetic Endpoint Will Cover Virtually All Chemicals: It is not described how these endpoints make a toxicity category. Do any of the listed endpoints create "toxicity" if they do not produce cancer, or other toxicity? Why is this a separate category? Again, *almost every chemical can fit this category at some dose*.

Definition of Genotoxic Endpoint Will Cover Virtually All Chemicals: As defined by OEHHA in the Draft, nearly every chemical will fall under the category of genotoxic concern. Some of the endpoints have no relevance to carcinogenicity. For example, what is the significance of genotoxicity if it does not lead to adverse effects? Further, most of the "other relevant data" endpoints may not be relevant to genetic mutation.

Limitations of OEHHA's Sources and Methodologies Approach:

- §4.a.i. identifies a substance as Class One if any document or authoritative body says a substance, or its metabolite, poses a hazard threat. This approach perpetuates hazard assessment errors without the option for appeal – i.e. many metabolites may cause effects at high doses, but may only be present at low doses from metabolism. Again, such an approach will not aid prioritization.
- §4.a.ii. says OEHHA will use a "weight of evidence" assessment for all endpoints *except* cancer, reproductive, or developmental effects. It does not say what approach will be used to evaluate those three endpoints. Given that "weight of evidence" assessments are the toxicological standard – and given the profound impact of a carcinogen characterization that is not based on a full, balanced, assessment of the available data, *OEHHA should use weight of evidence evaluations for all endpoints*. Further, a weight of evidence approach is more globally accepted, as reflected in the Occupational Safety and Health Administration (OSHA)'s proposed rule to modify the existing Hazard Communication Standard to conform to the United Nations' Globally Harmonized System of Classification and labeling of Chemicals (GHS). 74 Fed. Reg. 50279 (Sept. 30, 2009). Consistent with the GHS, OSHA's proposal adopts a weight of evidence approach.
- §4.b. The distinction between Class One and Class Two is not at all clear, and appears contradictory. The criteria in §4.a and §4.b appear to be essentially the same – e.g. IARC 2B (included in Class One) includes chemicals with "limited animal data," and thus also fits under Class Two in section §4.d.ii.
- §4.c. proposes to classify any chemical as Class One for carcinogenicity if any identified organization says it has *any* potential for carcinogenicity, including "possible carcinogen" or "potential carcinogen." However, application of this approach is inconsistent – i.e. IARC 2B (possible carcinogen) is included as an

identifier, but EPA's "suggestive evidence" classification is not. For the purposes and intent of the GCI, and *in the interest of consistency, only significant carcinogens (known/probable, or equivalent) should be included, and not substances of weak or questionable carcinogenic concern.* Again, such an approach does not support prioritization based on degree of hazard.

Conclusion

A hazard identification approach this all-inclusive cannot provide the necessary guidance required to ensure the GCI is an effective, scientifically grounded program. Implementation of the Draft in current form would result in the branding of thousands of substances that are inherently safe in their current applications and exposures. Rather than help prompt a thoughtful assessment of chemical applications that may *genuinely* pose a concern to the citizens of California, OEHHA's approach instead likely could prompt mass preemptive product de-selections, adding to the State's badly weakened economy, and drive more industries out of the State. Traditional and basic approaches to risk assessment are grounded in the evaluation of levels of exposure and the degree of hazard posed by various substances or practices. While we appreciate OEHHA's effort to ensure that it can evaluate any substance that may pose a hazard, the real goal of the proposed rule should be a coherent system for identifying degree of hazard based on a comprehensive understanding of relevant science coupled with prudent judgment as to the certainty of the risk being assessed.

SIRC hopes that a thoughtful revision of the Draft will result from comments such as ours. We further urge that OEHHA carefully consider the comments of organizations such as the Green Chemistry Alliance and the American Chemistry Council in reevaluating its approach to the original intent of this project.

Very truly yours,



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