



November 17, 2014

Ms. Monet Vela
Office of Environmental Health Hazard Assessment
P.O. Box 4010, MS-58D
Sacramento, CA 95812-4010

Submitted Electronically to: P65Public.comments@oehha.ca.gov

RE: Request for Public Participation on Potential Regulatory Actions

Dear Ms. Vela:

The National Coffee Association (NCA) appreciates the opportunity to submit comments in response to the California Office of Environmental Health Hazard Assessment's request for public participation on potential regulatory actions and priority level for each potential action in anticipation of OEHHA's planned workshop to discuss the next steps in its regulatory reform/update projects.

NCA represents the U.S. coffee industry, which generates \$36 billion annually in retail and foodservice sales, and conducts over \$5 billion in trade, including serving 29 million California consumers their morning coffee. NCA membership includes roasters, coffee growers, importers and exporters domiciled within and beyond the United States, including 42 headquartered in California and many more who conduct business in or through the state directly and/or through their suppliers, distributors and retailers.

The NCA joins in the comments filed by the California Chamber of Commerce Coalition. However, we feel we can add some perspective to the discussion based on the experience of our members.

Nearly five years ago, an individual who brings lawsuits in the name of an entity he created for this purpose filed a notice of intent to sue companies which sell and serve coffee. It quickly grew into a complaint against more than 100 defendants – companies that roast beans and/or sell coffee, including retailers who do nothing more than put these products on their shelves and sell them. That case has been litigated ever since.

The claim is based on the fact that roasting beans naturally produces acrylamide in brewed coffee at levels which, according to FDA tests, are approximately three to thirteen parts per billion. Acrylamide, which is present in most foods that are browned, is a listed chemical based on a 1990 IARC determination that it produces cancer in rodents. As a result, the claim is that there should be a cancer warning on coffee.

As it happens, there is a rich body of literature on coffee and cancer, as well as on dietary acrylamide. NCA has long followed the development of this body of literature and believes that it demonstrates that drinking coffee does not increase – and may decrease – the risk of cancer. These comments, however, do not address the meaning and application of the scientific coffee studies to Proposition 65 – that subject is currently being sorted out by the court and the parties.

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We reference the case and the background here solely because the NCA believes that this case is illustrative of a serious problem facing all companies that sell products (particularly foods) in California. It is that, in practice, the effect of Proposition 65 is very different from what the drafters and voters had in mind, as described in the Voter Pamphlet. Similarly, the regulations are different in application from what OEHHA and its predecessor agency intended, as described in the Statements of Reason underlying them.

Despite efforts to streamline and make the process more efficient, the coffee case has been litigated actively for nearly five years at common defense costs well into the seven figures, with individual defense costs adding further to the total. Discovery was served on nearly 100 companies, including depositions of some defendants' employees. Trial of the issues lasted two months – six weeks of which consisted of plaintiff's rebuttal experts. It is obvious from our experience – which we understand does not differ from the small handful of cases where defendants had the resources and endurance to litigate – that for thousands of companies against whom Proposition 65 claims are made, in fact for virtually any individual company, the affirmative defenses in the statute and regulations are completely illusory.

Companies who take a thoughtful and data-based analysis of whether their products require a warning and believe they have a sound scientific and/or legal basis for believing their products comply with Proposition 65 have no realistic means of obtaining an independent assessment which will actually protect them from having to litigate to prove the point. As the list of covered chemicals grows, it is difficult to imagine a product – particularly products the content of which are largely derived from nature – in which one cannot *detect* a Proposition 65 chemical, and thereby shift an economically unsustainable burden of proof onto the defendant. As a practical matter, that is generally the only showing required for plaintiffs to force defendants to make the choice between reformulating their product (regardless of whether it's possible) or putting a cancer or reproductive toxicity warning on their products. The defenses, which were meant to be limited to warnings for products which actually pose an unacceptable risk to the public, are not within the reach of any but a tiny number of defendants. The reality is that Proposition 65 warnings are much more likely to reflect the financial condition of a company than the risk posed by the product. No one benefits from such a system.

Fixing this by regulation may be difficult, but it is worth the effort to try. One could begin with a meaningful Safe Use Determination (SUD) process. Among other things, that process cannot mirror the courtroom, with OEHHA serving as prosecutor rather than as independent scientific decision-makers. The criteria and standards for obtaining an SUD should be known and should be reasonable. In court, for example, the standard defendants must meet is preponderance of the evidence. But it is unclear whether OEHHA requires preponderance of the evidence or something approaching certainty. The fact that OEHHA has not granted an SUD since 1998, and that most companies have given up trying to get one, suggests the latter.

OEHHA and the Attorney General should also consider how they can affect the incentive structure so as to discourage meritless claims and encourage efficiency. The only current policy or regulation remotely relevant to the subject is the Attorney General's policy that a settlement must require reformulation or a warning to meet the public benefit requirement. Thus, if a meritless claim is filed, the *only* options available for most companies are to put a warning on, or

to alter the constituency of, a product which complies with Proposition 65. This is plainly not what the voters were told. For the tiny handful of companies with the resources and the fortitude to endure litigation, the plaintiff is highly incentivized to make the process as expensive for the defendants as possible to get to a settlement so that it can collect its fees.

For example, a regulatory variation on an offer of judgment could be written to create a presumption that a company, which has made a good-faith determination before receiving a threat of lawsuit based on scientific literature and reliable data that its products do not require a warning, has not knowingly and intentionally caused an exposure that requires a warning. A regulatory provision that limits penalties and, more importantly, recovery of fees in that situation would be helpful and would encourage companies to undergo these analyses. As it currently stands, a company that takes a thoughtful approach to determining its obligations under the statute is in no better position than one that does not.

Finally, there is nothing in the Voter Pamphlet or in the statute which suggests the drafters or the voters intended that, as applied, Proposition 65 would end up treating industrial poisons the same way as foods that contain minute quantities of Proposition 65-listed chemicals either naturally or as a result of cooking, *and* the safety of which is regulated by FDA. Although the regulations purport to make a distinction, until the problems described above are addressed, they will not be usable by the vast majority of companies which do business in California – and the results will continue to be unintended, in fact likely unimagined, by the voters.

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Thank you for the opportunity to provide these comments on behalf of our members. Please do not hesitate to contact us if we may be of assistance.

Respectfully submitted,

A handwritten signature in blue ink that reads "William M. Murray". The signature is written in a cursive style with a prominent underline at the end.

William M. Murray, CAE
President and CEO