

KYLE PITSOR

Vice President, Government Relations

April 8, 2015

Monet Vela
Office of Environmental Health Hazard Assessment
P. O. Box 4010
1001 I Street
Sacramento, CA 95812-4010

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

RE: CLEAR AND REASONABLE WARNING REGULATIONS

Dear Ms. Vela:

The National Electrical Manufacturers Association (NEMA) is the trade association representing the interests of the U.S. electrical equipment and medical imaging industry.¹ NEMA members have more than 170 facilities (headquarters, manufacturing, research, sales or distribution offices) in California and are a significant contributor to the state's manufacturing and technology sector.

NEMA appreciates the opportunity to comment on the Office of Environmental Health Hazard Assessment's (OEHHA) Notice of Proposed Rulemaking to Article 6 in Title 27 of the California Code of Regulations pursuant to the Safe Drinking Water and Toxic Enforcement Act (Proposition 65 or "Prop 65"). We recognize the considerable effort OEHHA has invested in evaluating the regulatory framework underlying Prop 65 and remain hopeful that the final changes will reduce the burdensome impact this program has imposed on manufacturers while retaining its value to California residents.

Unfortunately, the latest version of the proposal would not achieve this objective. NEMA generally agrees with the California Chamber of Commerce ("the Chamber") that contrary to OEHHA's stated intent the proposal will make Prop 65 compliance **more** difficult and costly. In general we are concerned that:

- The proposal reflects two apparently conflicting goals – simultaneously allowing flexibility in how manufacturers achieve "clear and reasonable" warnings while providing "*more specificity*" regarding the minimum elements required in warnings. These goals are ambiguous and confusing and must be reconciled prior to promulgation so that manufacturers will be certain of their obligations.
- Manufacturers would be **more** vulnerable to litigation – not less – as a result of the proposal. This is because the rule changes open a new field of challenge pertaining to whether warnings satisfy the new requirements. Litigation in the past has almost always centered on whether a warning should or should not be provided, not the content.
- OEHHA's contention that the proposal "*does not impose any new requirements upon private persons or business*" and thus will not have a significant economic impact is almost certainly erroneous. Preliminary results from an economic analysis sponsored by the Chamber indicate that the proposed changes to Article 6 could force up-front costs of \$390 - \$750 million **in the first years of implementation**.² These costs will stem from the increased specificity required

¹ See www.nema.org

² "The Business Cost of Proposed Changes to Article 6 of Proposition 65," – preliminary results. Andrew Chang & Co. LLC; March 2015.

in the warnings, additional testing for the 12 “listed” chemicals cited in the proposal, and increased litigation.

The proposal suggests that OEHHA retains the authority to amend this list of 12 chemicals at any time, thus creating continual uncertainty for manufacturers and other regulated parties as to which new substances to test for and identify. In addition, the inclusion of “phthalates” in the list is problematic because it potentially encompasses hundreds of substances that are not now on the Prop 65 list.

NEMA also urges OEHHA to make clear that warnings can be placed in owner’s manuals, instructions for use, or other documents that accompany products to satisfy a manufacturer’s labeling obligation. Many complex products in the electrical sector already contain product labels – at times more than one - that are limited in size and densely populated with other disclosures required by state or federal law or industry standards. This concern is exacerbated by the requirement that Prop 65 warnings be provided in multiple languages when other labels are multi-lingual, as would be the case for products sold in Canada.

With regard to medical imaging devices, NEMA believes products in this sector should be given a “safe harbor” option under Prop 65 similar to prescription drugs. This is appropriate because the principle objectives of Proposition 65 – “Right to Know” and consent of the consumer - are achieved by the fact that medical devices are dispensed *via* prescription by medically licensed personnel – a process recognized and controlled by the State of California.

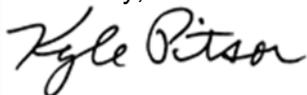
Moreover, the U.S. Food and Drug Administration (FDA) regulates the marketing and sale of medical devices extensively through the Medical Device Amendments (“MDA”)³ to the Food, Drug and Cosmetic Act (“FDCA”)⁴. These rules exist to ensure that devices (and drugs) are safe and effective and they ***expressly preempt*** state law requirements governing medical devices to ensure national uniformity in product regulation -.

Thus retaining medical devices within the scope of Prop 65 creates a fundamental conflict. On the one hand, a device manufacturer who has provided FDA with sufficient evidence to determine a product is both safe and effective is therefore allowed under Federal Law to market the device in interstate commerce. Yet Prop 65 would compel the manufacturer to label the same device with a warning indicating something to the contrary.

For these reasons, we respectfully request that devices subject to the jurisdiction of, and approved for use by, the U.S. Food and Drug Administration be granted an exemption under the proposed rule.

If you have questions about these comments or seek additional information about our industry, please do not hesitate to contact Mark A. Kohorst of NEMA Government Relations (mar_kohorst@nema.org, 703-841-3249)

Sincerely,



Kyle Pitsor

Vice President, Government Relations

³ 21 U.S.C. § 360c, *et. seq.*

⁴ 21 U.S.C. § 301, *et. seq.*