July 5, 2018

Monet Vela
Office of Environmental Health Hazard Assessment
1001 I Street, 23rd Floor
Sacramento, California 95812-4010
via electronic submission

Re: Comments of the American Chemistry Council regarding
Proposed Amendments to Proposition 65"Safe Harbor" Warning Regulations relevant to certain pesticide products

Dear Ms. Vela:

The American Chemistry Council (ACC) is pleased to submit these comments on the proposed amendments to the regulations establishing "safe harbor" Proposition 65 warnings for certain pesticide products.[1] ACC represents the business of chemistry in the United States, including many manufacturers of chemistries regulated as pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as well as the California Department of Pesticide Regulation (DPR).[2]

ACC agrees that the current Proposition 65 safe harbor regulations for consumer products conflict with the U.S. Environmental Protection Agency's (EPA's) requirements for pesticide labeling under FIFRA. OEHHA's current proposal, however, does not resolve the conflict, introduces new problems, and makes the availability of the safe harbor inappropriately contingent on the actions of a third party (EPA) that California cannot control.[3] We urge OEHHA to consider an alternative approach to resolve the noted conflict.

---

[1] Proposed Amendments to Article 6 Clear and Reasonable Warnings, April 2018.

[2] ACC's constituencies include the Center for Biocide Chemistries (CBC) (formerly known as the Biocides Panel), which is composed of more than 50 companies that manufacture and formulate antimicrobial pesticides for use in industrial processes, material preservation, marine antifouling, industrial water treatment, public health applications and numerous other uses. The CBC focuses on the broad range of scientific, regulatory, legislative, legal and educational issues unique to antimicrobial pesticides, as well as those issues affecting all pesticide products. ACC is also home to the Chlorine Chemistry Division, which represents major producers and users of chlorine in the United States. Chlorine has a broad suite of uses as a disinfectant, such as in drinking water, wastewater, swimming pools, food production and preparation, and medical applications.

[3] Proposition 65 requires a clear and reasonable warning prior to exposure to a listed chemical. The law therefore has to be interpreted to allow a fair and achievable path to delivering a clear and reasonable warning in each case – it cannot, as a matter of basic constitutional due process, demand a warning where it is impossible for anything to ever legally constitute that warning. Indeed, Section 3531 of the California Civil Code famously says, "[t]he law never requires impossibilities." On June 28, 2018, in National Shooting Sports Foundation, Inc., v. California, the California Supreme Court offered a helpful discussion of when compliance with a statutory requirement is excused due to the impossibility of meeting the requirement. http://www.courts.ca.gov/opinions/documents/S239397.PDF

ED_002519_00020497-00001

Alternative Proposal

Specifically, we note that like pesticide products, prescription drugs are also subject to a complex federal regulatory program that requires a federal agency to approve the specifics of the label for the regulated product before the product can enter commerce. To resolve the same problem OEHHA has identified between Proposition 65 and FIFRA warnings and label statements, the agency promulgated a safe harbor regulation that accepts otherwise federally-compliant labels for a prescription drugs as clear and reasonable warnings for Proposition 65 purposes:

> § 25607.7 Prescription Drug Exposure and Emergency Medical or Dental Care Exposure Warnings
>
> (a) For prescription drugs, the labeling approved or otherwise provided under federal law or the prescriber's accepted practice of obtaining a patient's informed consent complies with this article.

To our knowledge, the prescription drug provision has been successful and has reduced compliance burdens for business. At the same time, it puts a premium on covered businesses achieving 100% compliance, since there remains Proposition 65 liability exposure for any label that has not been federally approved - for any reason.

We encourage and support OEHHA adopting a consistent and conceptually identical approach for FIFRA-regulated pesticide products. The regulation could simply provide as follows:

> § 25607.XX Pesticide Exposure Where Labels or Labeling Are Approved under Federal and State Law
>
> (a) For pesticide products registered by the United States Environmental Protection Agency pursuant to the Federal Insecticide, Fungicide and Rodenticide Act, the label approved by the Administrator of that federal agency complies with this article.

Rationale for Need for Alternative Proposal

1. The Yellow Triangle Warning Symbol Proposed by OEHHA is not Consistent with FIFRA Labeling Requirements.

FIFRA regulations and guidance do not allow the use of a pictogram for pesticide products. This issue has been raised in the context of the use of GHS pictograms, and EPA has been quite clear that GHS pictograms are prohibited in FIFRA-approved labels. As a practical matter, this makes it impossible for industry to comply with or use the proposed warning regulations. We therefore support modification of the warning regulation as discussed above. It is not sufficient to simply delete the proposed requirement for a yellow triangle pictogram.

2. The Signal Word Proposed by OEHHA is Not Consistent with FIFRA Labeling Requirements.

As OEHHA has correctly noted, the use of the FIFRA Signal Word "WARNING" in FIFRA-approved labels has a limited and specific meaning related to certain acute health effects in a risk-based paradigm. EPA does not approve use of the three FIFRA Signal Words, "caution," "warning," and "danger" outside

this context. However, as noted in these comments, merely substituting the term "warning" with entirely different word in the Proposition 65 warning regulations does not address the fundamental basis for the conflict between OEHHA's proposal and FIFRA.

3. OEHHA's Proposal Does Not Fundamentally Resolve Underlying Conflicts.

In the context of FIFRA-approved labels, conflicts are no small matter. EPA has been clear that "warnings, precautions or any other information that conflict with the FIFRA-approved label…could be misleading to users of the pesticide and therefore cause the pesticide to be considered misbranded and unlawful for sale or distribution."[4] [emphasis added]. In any particular case, adding a Prop 65 warning to a product that otherwise has been approved under FIFRA to meet its standards (such that the product does not present a significant risk to human health and the environment[5]) could actually be considered misleading.[6] There is thus no reasonable certainty that EPA can or would approve the inclusion of a Proposition 65 warning statement on a pesticide label under the facts in any particular case. The current proposal, therefore, cannot deliver the certainty needed to offer a viable compliance path and does not achieve the objective set forth by OEHHA in engaging in this rulemaking – namely to provide a means for pesticide registrants who wish to provide a Proposition 65 warning on their product label to do so without incurring a conflict with EPA.[7] OEHHA simply cannot reasonably predict that the addition of any Prop 65 warning to a FIFRA label will be approved, and thus its safe harbor regulation cannot be contingent on this uncertain and future condition.

***

Thank you for the opportunity to comment. ACC would be pleased to participate in additional stakeholder discussions to explore a solution to the conflict noted by OEHHA if needed. If you have any questions, please contact me at Tim_Shestek@americanchemistry.com.

Very truly yours,

Tim Shestek
Senior Director, State Affairs
American Chemistry Council

cc: Lauren Zeise, Ph.D., Director
Allan Hirsch, Chief Deputy Director

---

[4] Office of Pesticide Programs, Label Review Manual, 3-4, available at https://www.epa.gov/sites/production/files/2016-12/documents/lrmcomplete.pdf

[5] See FIFRA §§ 2 and 3.

[6] Fundamentally, businesses should not be required to deliver a warning about a product implying a significant or material health or environmental risk that conflicts with a FIFRA determination to the contrary. Beyond that, the regulation should offer a meaningful, viable, and predictable path to compliance.

[7] See Initial Statement of Reasons, Proposed Amendments to Article 6 Clear and Reasonable Warnings, April 2018.