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July 5, 2018

VIA https://oehha.ca.gov/comments/

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

Re: Comments on Proposed Amendments to Title 27, Article 6, Section 25603, California Code of Regulations - Consumer Product Exposure Warnings

Dear Ms. Vela:

Albaugh, LLC submits these comments in response to the Notice of Proposed Rulemaking dated April 27, 2018 issued by the California Office of Environmental Health Hazard Assessment ("OEHHA") with respect to proposed amendments to the Proposition 65 "safe harbor" warning regulations, Title 27, Article 6, Section 25603, California Code of Regulations (the "Proposed Amendments").

Albaugh, founded in 1979 (as Albaugh Chemical Corporation) by Dennis Albaugh, is recognized as the largest privately-held U.S. company specializing in the production and packaging of post-patent crop protection products. Albaugh's business in the United States encompasses sales throughout the country, including in California, of products registered pursuant to the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"). Albaugh's products are marketed principally for agricultural use in pre- and post-planting applications, post-harvest and seed treatment uses. Albaugh also markets its products for use in specialty applications, such as turf and ornamental uses, and for industrial vegetation management.

Albaugh supports the comments on the Proposed Amendments that are submitted by CropLife America ("CLA"), the Council of Producers & Distributors of Agrotechnology ("CPDA"), and other trade associations. In addition, Albaugh would like OEHHA to know that, based upon recent experience, Albaugh believes that the Proposed Amendments will not fulfill the stated intention to resolve conflicts with existing federal regulations and practice that govern the approval of pesticide labeling by the United States Environmental Protection Agency ("EPA"). Albaugh also believes that the requirements of the California Department of Pesticide Regulation ("DPR") will block the adoption of the proposed new safe harbor wording on pesticide products sold in California until the conflicts with EPA are resolved.

On August 30, 2016, OEHHA adopted new Article 6 Clear and Reasonable Warning regulations that are to become effective on August 30, 2018. Those regulations among other things set forth specific "safe harbor" methods for delivering "clear and reasonable" warnings for consumer product exposures to products covered by Proposition 65, which methods included the use of the

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word "WARNING" in safe harbor warning statements. Subsequently, OEHHA identified that such prescribed safe harbor language poses a conflict with FIFRA with respect to consumer pesticide products, because EPA regulations specify the use of the same word "WARNING" on pesticide product labels for a different purpose. The Proposed Amendments would allow registrants of Proposition 65-covered pesticide products to issue a safe harbor warning by substituting the words "ATTENTION" or "NOTICE", instead of the word "WARNING". In OEHHA's view, this amendment to Proposition 65 regulations resolves the aforementioned conflict.

The intentions of OEHHA are clear and appreciated by pesticide registrants like Albaugh that desire to take advantage of safe harbor warning opportunities with respect to its products that are subject to Proposition 65 in California. However, in order to revise the labeling for its products in almost any respect, a pesticide registrant must obtain the approval of the relevant federal and state agencies (typically via an application to amend the product label, or in some cases via a "notification" to the regulatory agency where such agency determines that an express approval is not necessary). This is no less true with respect to adding the OEHHA-prescribed safe harbor warning language than for other types of changes to label text. The Proposed Amendments take for granted that registrants of pesticide products will not encounter difficulties in obtaining the necessary approval of EPA and the California DPR to add the safe harbor language to the labels for such products. In Albaugh's experience, this has not been the case.

Some months ago, in anticipation of the August 30, 2018 effective date for the 2016 amendments to Article 6, Albaugh submitted to EPA via the notification process revised label language for several Proposition 65-covered products to include the safe harbor wording of Section 25603[1]. Chapter 7 of EPA's Label Review Manual appears to contemplate that such a notification process is appropriate to utilize for such label changes. However, EPA label reviewers rejected those notification submissions and instructed Albaugh to resubmit them as applications for label amendment. Albaugh did as instructed, and two of such amendment requests were approved, but surprisingly the rest were rejected as "unnecessary", notwithstanding the fact that EPA had requested those submissions. Two EPA reviewers have informed Albaugh that the issue is still under discussion within EPA and with DPR, and that requests for label amendments are being "held" until the matter is decided; in the meantime, EPA is not processing either notifications or "fast-track" amendments to add Proposition 65 language. Hence, at best, there does not appear to be consensus within EPA as to how to handle the issue of adding OEHHA's proposed safe harbor wording to pesticide labels.

At the same time, the DPR is requiring registrants in California that desire to add the new OEHHA language to submit evidence of EPA notification or approval of a label amendment. Albaugh has 2 notifications pending before the DPR to add the new OEHHA safe harbor wording that DPR will not process until Albaugh submits evidence to show that such change was approved at EPA.

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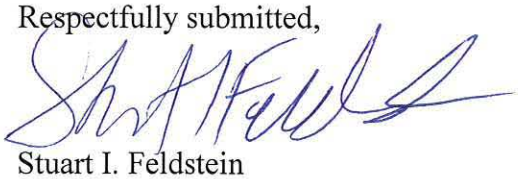
[1] The requested safe harbor language was not the language contained in the Proposed Amendments, but rather was the language promulgated by OEHHA in 2016, prior to the April 2018 Notice of Proposed Rulemaking.

We assume that we are not alone in this experience. Consequently, registrants are caught in a "catch 22" situation between different regulatory bodies with no consensus on the proper course of action to follow. The robust plaintiffs' bar in California, alert to opportunities to collect recoveries for perceived inadequacies in Proposition 65 compliance, makes mandatory the inclusion of the safe harbor wording on pesticide product labeling, yet at this time the pathway for registrants to follow in order to utilize the proposed safe harbor language is far from clear.

In Albaugh's view, at a minimum, action on the Proposed Amendments must be deferred temporarily and the effective date of the 2016 amendments should be postponed for FIFRA-regulated products until the path for obtaining the requisite approvals for the inclusion of the proposed safe harbor warning language on pesticide labeling is made clear and agreed upon by EPA and DPR. Additionally, consistent with Section 25600(b) and as noted in OEHHA's "Questions and Answers for Businesses" document dated August 2017, it should be made clear that products manufactured in the period prior to the future effective date of the Proposed Amendments may continue to comply with the September 2008 version of the regulations, so that such products need not be recalled for relabeling, particularly in this unsettled regulatory environment.

Thank you for the opportunity to submit these comments, and please do not hesitate to contact me should you have any questions about this comment letter.

Respectfully submitted,



Stuart I. Feldstein
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