July 5, 2018

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Submitted via https://oehha.ca.gov/comments/

Re: Proposed Amendments to Proposition 65"Safe Harbor" Warning Regulations

Dear Dr. Zeise and Ms. Monahan-Cummings:

On behalf of CropLife America (CLA),[1] RISE (Responsible Industry for a Sound Environment)®,[2] the Household & Commercial Products Association (HCPA)[3] and the Council of Producers & Distributors of Agrotechnology (CPDA),[4] thank you for this opportunity to comment on the proposed amendments to the regulations establishing "safe harbor" Proposition 65 warnings for

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[1] CLA, established in 1933, represents the developers, manufacturers, formulators and distributors of plant science solutions for agriculture and pest management in the United States. CLA's member companies produce, sell and distribute virtually all the crop protection and biotechnology products used by American farmers.

[2] RISE is the national not-for-profit trade association representing more than 220 producers and suppliers of specialty pesticide and fertilizer products to both the professional and consumer markets. RISE member companies manufacture more than 90 percent of domestically produced specialty pesticides used in the U.S., including a wide range of products used on lawns, gardens, sport fields, and golf courses to protect public health.

[3] HCPA (formerly the Consumer Specialty Products Association) is the premier trade association representing companies that make and sell products valued at $180 billion annually that are used for cleaning, protecting, maintaining, and disinfecting in homes and commercial environments. HCPA members employ 200,000 people in the U.S. whose work helps consumers and workers create a cleaner, healthier and more productive life. HCPA's mission is to protect, promote and enhance the household and commercial products industry and consumers and workers who use our members' products. HCPA members register, sell and distribute pesticide products in California.

[4] CPDA is the premier advocate for agricultural adjuvant and inert ingredient suppliers. CPDA provides legislative and regulatory support to formulators, distributors and manufacturers of post-patent pesticide products and biorationals. CPDA members produce and sell tank-mix adjuvants, inert ingredients, pesticides and other agrotechnology products across the U.S., and range in size from small businesses to large, publicly traded companies. Approximately 80% of the inert ingredients used in agricultural production products throughout the U.S. are provided by CPDA members.

certain pesticide products (the "Proposed Amendments") that are regulated by the United States Environmental Protection Agency (US EPA) pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and by the California Department of Pesticide Regulation (DPR). The Proposed Amendments are described in OEHHA's April 27, 2018 Notice of Proposed Rulemaking (NPR).

I. INTRODUCTION AND SUMMARY

CLA, RISE, HCPA and CPDA agree with OEHHA that the current Proposition 65 safe harbor regulations for consumer products conflict with US EPA requirements for pesticide labeling under FIFRA. As the Initial Statement Reasons ("ISOR") for the Proposed Amendments states, "pesticide registrants who wish to provide a Proposition 65 warning on their product label are unable to provide a safe harbor warning under Article 6 [of the Proposition 65 regulations]."[5] We agree with OEHHA that amending the Proposition 65 regulations may provide an appropriate vehicle for resolution. We are unable, however, to support the Proposed Amendments in their current form.

The NPR identifies US EPA's use of the signal word "WARNING" as the basis for conflict, because it has a specific meaning in the FIFRA labeling-and-warning scheme, where it is reserved to identify acute toxicity characteristics in Toxicity Category II.[6] The Proposed Amendments purport to resolve this conflict by allowing federal pesticide registrants selling products in California to modify the current safe harbor Proposition 65 warning to use alternative "signal words"—"ATTENTION" or "NOTICE"— as a substitute for "WARNING." According to the NPR, the use of "ATTENTION" or "NOTICE" would resolve the conflict between federal and state requirements and provide registrants with the benefit of the safe harbor to protect themselves from lawsuits under Proposition 65.

The Proposed Amendments frame the conflict too narrowly and do not address more fundamental underlying issues, which include: (1) the different purposes of the warnings under the two schemes and the criteria for deciding when such warnings are required, and (2) the primacy of FIFRA labeling requirements, which foster uniformity in warnings throughout the United States and relieve interstate producers from duplicative burdens to obtain multiple approvals from state and federal agencies. The Proposed Amendments further overlook a practical issue arising from OEHHA requirements for and US EPA prohibitions against certain "pictograms."

In this comment, we propose alternatives for a safe harbor that would allow registrants to provide carcinogenicity and reproductive toxicity hazard statements to consumers in a consistent, systematic manner, and also resolve the underlying conflicts between the FIFRA label-warning system and Proposition 65 requirements. Specifically, OEHHA could achieve its intended objective by amending Proposition 65 regulations to provide that:

(a) labels approved by the US EPA for pesticide products would be deemed to comply with

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5 ISOR, Proposed Amendments to Article 6 Clear and Reasonable Warnings, April 2018.

6 *See* 40 CFR 156.62 ("This section establishes four Toxicity Categories for acute hazards of pesticide products.").

Proposition 65;

(b) a reference to US EPA risk assessments for Proposition 65 toxicity endpoints would satisfy Proposition 65; or

(c) US EPA-approved labels in combination with warnings on Safety Data Sheets (SDS) that comply with the federal or state Hazard Communication Standard or the Worker Protection Standard for pesticides satisfy Proposition 65.

II. OBJECTIONS TO PROPOSED AMENDMENTS

A. The Proposed Amendments will compel federal registrants to add to their FIFRA-regulated labels state warning statements that conflict with federal requirements.

The Proposed Amendments take a flawed approach in addressing conflicts between federal and state labeling requirements, requiring federal registrants to seek US EPA approval to add to their labels state-required information that US EPA does not require and may not approve. The Proposed Amendments also frame the conflict too narrowly. Proposition 65 is intended to provide information regarding potential ***hazards***, regardless of whether risks are present. FIFRA's label-warning system is designed to communicate information to mitigate ***risks***.[7] To view the conflict as the result of inconsistencies regarding the use of the signal word "WARNING," and nothing more, ignores federal law that regulates pesticide labeling and a fundamental conflict far more important than divergent uses of the same signal word.

Specifically, US EPA registration of a pesticide product is based on a finding that the product "will perform its intended effect without unreasonable adverse effects on the environment." FIFRA § 3(c)(5)(e). "Environment" includes human health,[8] and cancer and reproductive toxicity are considered "unreasonable adverse effects" *per se*. For pesticides used on agricultural commodities, registration requires a "tolerance," or a level determined to be "safe," resulting in "a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." 21 U.S.C. § 346a(b)(2)(A)(ii). As a general matter, the levels of exposure permitted under FIFRA are significantly ***less*** than the "warning thresholds," *i.e.*, the lowest levels of exposure for which a warning is required under Proposition 65.

It is not merely the inconsistency in signal words that makes Proposition 65 warnings inappropriate. Under these standards, a US EPA decision to register a product is tantamount to a determination that the exposure to a Proposition 65-listed chemical from the use of that product in a manner consistent with the labeling precautions and instructions for use *does not reach the level of exposure that would require a Proposition 65 warning*. Given the risk-based nature of the FIFRA

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7 "The term 'unreasonable adverse effects on the environment' means . . . any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." FIFRA 2(bb).

8 "The term 'environment' includes water, air, land, and all plants and man and other animals living therein . . . ." FIFRA 2(j).

registration scheme and its label-warning system, a Proposition 65 warning on the label of a product implicitly contradicts not only the use instructions and precautionary statements that FIFRA requires and US EPA has approved, but also the registration itself.

Although the prohibition from "exposing" an individual in California to a chemical "known to the state of California to cause cancer or reproductive toxicity" without a warning provides for an exemption where the level of exposure is beneath prescribed warning thresholds, the statute places the burden on the business to prove that the level has not been exceeded or that the warning it has provided is "clear and reasonable." Cal. Health & Safety Code §§ 25249.6, 25249.10(c). If OEHHA adopts the Proposed Amendments, the safe harbor label warning will, in effect, not be optional. As a practical matter, the state warning will become mandatory: federal registrants will be compelled to use it because it will be the only warning that will foreclose Proposition 65 litigation. Proposition 65 and/or safe harbor warnings may not compel speech that is controversial or not factual. For these reasons, a Proposition 65 warning on a FIFRA-registered product, absent some unusual and compelling circumstances, directly contradicts the US EPA approved precautionary language and use directions and product registration and cannot be viewed as factual or uncontroversial.

B. Even if the Proposed Amendments were successful in resolving conflicting requirements for warning signal words, the yellow triangle warning symbol pictogram is not permitted under US EPA labeling requirements.

The warning symbol that the Proposed Amendments would require, both for the "long form" and "short form" warnings required under the present safe harbor regulations, is inconsistent with US EPA labeling requirements. According to the Final Statement of Reasons, OEHHA considered requiring a similar pictogram developed under the Globally Harmonized System (GHS) before it chose the yellow triangle, because GHS had been adopted by many government agencies already (indeed, GHS has become the foundation for modern SDS required under the Occupational Safety and Health Act and its Hazard Communication Standard).[9] US EPA, however, does not permit GHS statements and pictograms for pesticide product classification and labeling.

US EPA explains:

> "The Globally Harmonized System of Classification and Labeling of Chemicals ("GHS") is a worldwide initiative to promote standard criteria for classifying chemicals according to their health, physical and environmental hazards. It uses pictograms, hazard statements, and the signal words "Danger" and "Warning" to communicate hazard information on product labels and safety data sheets in a logical and comprehensive way.
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> "EPA has not adopted GHS for pesticide product classification and labeling. In most cases, ***GHS hazard statements and pictograms should not appear on pesticide product labels sold and distributed in the United States.*** . . . If adopted, GHS will provide an

[9] FSOR, Proposed Repeal of Article 6 and Adoption of New Article 6 Regulations for Clear and Reasonable Warnings, at100-103,

internationally consistent basis for classifying chemical hazards. Once hazards are classified, GHS will also ensure that signal words, pictograms and hazard statements have the same meaning in all settings, domestically and internationally."[10]

In Pesticide Registration Notice 2012-1,[11] US EPA further explains the conflict between the use of pictograms required under the GHS and FIFRA pesticide labeling requirements. US EPA noted significant "differences between EPA's current requirements and the GHS related to ***classification criteria***, ***hazard statements, pictograms,*** and ***signal words***" and the need "to avoid potential inconsistencies between EPA-approved labels for pesticides regulated under [FIFRA] and the SDSs that OSHA requires for these chemicals under the HCS."[12] US EPA further noted that CLA and the American Chemistry Council Biocides Panel submitted comments at the OSHA hearing "urging that OSHA and EPA coordinate their approaches and that pesticides be exempted from the OSHA rule . . . until EPA updates its regulatory requirements to be consistent with the GHS." In response, US EPA and OSHA "worked together to develop the guidance in [the] PR Notice to address these commenters' comments."[13]

The purpose of PR Notice 2012-1 was to "explain[] how (federal) registrants can comply with both agencies' requirements."[14] US EPA urged federal registrants to include FIFRA labeling information in the SDS and to include additional information that did not conform to the labeling information in the "Section 15 of the SDS ("Regulatory Information") [as] an appropriate place to insert this information."[15] "To follow [this recommendation], registrants should reprint the FIFRA hazard statements . . . , signal word, and symbol (if required) in Section 15 ("Regulatory Information") . . . ." In sum, EPA recognizes a conflict between the GHS and FIFRA warning systems and the yellow triangle pictogram that is part of the safe harbor warning set forth in OEHHA's Proposed Amendments.[16]

C. The Proposed Amendments will invite other states to impose their own requirements for state-specific warnings and label statements.

To our knowledge, no state currently attempts to compel registrants to include state-specific warnings on their US EPA approved labeling. The Proposed Amendments will compel registrants to do

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[10] US EPA, Pesticide Labels and GHS: Comparison and Samples, available at https://www.epa.gov/pesticide-labels/pesticide-labels-and-ghs-comparison-and-samples last updated on February 16, 2018 (emphasis added).

[11] Pesticide Registration Notice 2012-1, "Material Safety Data Sheets as Pesticide Labeling," US EPA, April 2012-1, available at https://www.epa.gov/pesticide-registration/prn-2012-1-material-safety-data-sheets-pesticide-labeling.

[12] PR Notice 2012-1 at 1.

[13] *Id*. at 4.

[14] *Id*. at 5.

[15] *Id*. at 4.

[16] The requirement for the yellow triangle pictogram and the GHS both were discussed extensively in the public comment phase of the rulemaking for the safe harbor regulations, and in the ISOR and the Final Statement of Reasons. No mention was made of the conflict between the requirement for GHS pictograms and US EPA's label requirements.

so and will serve as precedent for other states to follow. The FIFRA label-warning system cannot tolerate competing requirements in numerous states because it would create confusion among distributors, retailers, consumers, and even regulators, and would be a tremendous burden on US EPA.

We acknowledge and know that OEHHA is placing reliance on a statement in the US EPA Labeling Review Manual (the "Manual") suggesting to registrants in California that the substitution of signal words may be appropriate to mitigate conflicts between requirements under Proposition 65 and the FIFRA labeling requirements. At the same time, US EPA acknowledges that it has "historically denied" applications to insert Proposition 65 warning statements on labels. US EPA Label Review Manual at 7-4. Indeed, some federal registrants may have submitted applications for amendments in the past, and US EPA may have granted some of those requests. This does not resolve the conflict from a policy standpoint, however, or relieve federal registrants from the jeopardy that would be imposed upon them by the Proposed Amendments.

Indeed, the Manual expressly indicates that it does not establish "new requirements, policies, or guidance." *Id*. at 1-3. Furthermore, recent information from US EPA indicates that its Office of Pesticide Programs is presently denying applications to include Proposition 65 statements. US EPA regulations, and not OEHHA regulations, remain the authority for determining what information will appear on the label for a FIFRA-regulated product. Until there is a declaration of policy to the contrary, the conflict referred to in the ISOR remains.

III. SUGGESTED ALTERNATIVES

New safe harbor regulations for other specific types of products take effect on August 30, 2018. These regulations provide some valuable precedents and examples for creating a safe harbor for pesticides. Indeed, these new regulations for other products take into account several fundamental principles that ought to be applied in crafting a regulation specific to pesticides.[17] Given that OEHHA has established these new regulations for other products, it follows that it would not be burdensome for OEHHA to craft similar regulations for pesticide products.

First, a safe-harbor warning for pesticides should be well-grounded within the FIFRA label warning system, so that federal pesticide registrants can be assured that it will be approved by US EPA and not questioned by California DPR or any other state or territory within the United States.[18] The Proposed Amendments are flawed because the change in US EPA policy that they contemplate would require US EPA to amend existing FIFRA labeling regulations through notice-and-comment

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[17] *See* Cal. Code Regs., *tit*. 27, § 25607.3 (declining to impose label requirements for alcoholic beverages in deference to federal labeling requirements); § 25607.7 (accepting labeling approved by federal law for exposure to prescription pharmaceuticals); § 25607.14 (allowing warnings in owner's manuals for equipment whose use causes exposure to diesel exhaust); and § 25607.16 (allowing warnings in owner's manuals for automobiles for exposures that occur during operation of a motor vehicle).

[18] State governments, including California, have authority to enforce FIFRA labeling requirements, so whatever authority OEHHA ascribes in its proposal to California DPR, including the authority to prosecute manufacturers for the sale of pesticides that may be "misbranded" due to labeling that deviates from that approved by US EPA and other pertinent state authorities.

rulemaking, because the current regulations prescribe toxicity warnings only for acute hazards of pesticide products. *See supra*, n. 6 and accompanying text (regarding use of "WARNING" to refer to acutely toxic effects). In this regard, a safe harbor should be self-effectuating. Federal registrants should not need to ask US EPA to bend its rules or ignore its policies to grant permission to add a state warning, or be dependent on US EPA's exercise of discretion in the approval, and thus leave open the possibility that US EPA may not approve it.

Further, a safe harbor warning should be amenable to the "notification" process used by US EPA and a similar process to be established by DPR, so that federal registrants will not be subjected to a delay in the registration process while US EPA and DPR review a request for an amendment to a product label.[19]

A. Revise the regulations so that the labeling approved for pesticides by US EPA is deemed to satisfy Proposition 65.

Section 25607 of the new safe harbor warning regulations, entitled "Specific Product, Chemical and Area Exposure Requirements," identifies several different types of products for which OEHHA has crafted product-specific safe harbor warnings, as noted above. For example, **§** 25607.7 leaves the matter of cancer and reproductive toxicity warnings for exposure to prescription drugs to be addressed by FDA label and warning requirements, as follows:

> **"§ 25607.7 Prescription Drug Exposure and Emergency Medical or Dental Care Exposure Warnings**
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> Section 25607.7(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."

A safe harbor for US EPA-regulated pesticides could follow this model. Such a regulation could be worded as follows:

> **§ 25607.XX Pesticide Exposure Where Labels or Labeling Are Approved under Federal and State Law.**
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> Section 25607.XX(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 and by the Director of the California Department of Pesticide Regulation pursuant to California law complies with this article.

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[19] Processing times for routine amendments of this nature may take several months at US EPA, and that applications for routine amendments may take six months to a year at California DPR. To alleviate such delays, the US EPA allows very minor amendments upon "notification" to US EPA without review and approval. California does not allow such a procedure, however. *See* 40 C.F.R. § 152.44 (requirements for application to approve change in labeling); § 152.46 (changes permitted by notification and not requiring notification).

This language tracks safe harbor language for prescription drugs and would not be burdensome for OEHHA to craft or registrants to implement.

B. Alternatively, the Proposed Amendments could be revised to provide that cancer and reproductive toxicity assessments contained in US EPA's online health assessment for any particular pesticide are "clear" for purposes of Proposition 65.

As noted above, Proposition 65 requires that a product complies with the regulations or that the label warning be "clear and reasonable." The Proposed Amendments could be drafted to provide that any informational statements regarding cancer or reproductive toxicity endpoints that appear in US EPA's online health assessment (and prepared for and referred to on the label approved by US EPA) "complies with" or is "clear and reasonable" for purposes of Proposition 65. Suggested wording follows:

> **§ 25607.32 Exposure to Pesticide Products Where Risk Assessment Approved by US EPA Is Available Online and Referred to on Label**
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> Section 25607.32(a) For pesticide products evaluated and registered by the United States Environmental Protection Agency pursuant to the Federal Insecticide, Fungicide and Rodenticide Act, an EPA health assessment for a pesticide, which addresses cancer or reproductive toxicity endpoints that is available on an Agency website information or statement that appears on the label for such product, as approved by that federal agency [complies with] [is clear and reasonable for purposes of] this article.

Further, with minor changes, the Proposed Amendments could implicitly acknowledge the conflict between Proposition 65 warning requirements for consumer products and the labeling requirements for pesticides under the FIFRA label warning scheme. The Proposed Amendments could indicate that a reference on a label to US EPA risk assessments for carcinogenicity and/or reproductive toxicity endpoints are deemed to be "clear and reasonable" for purposes of Proposition 65. For example, wording of the Proposed Amendments could be altered as follows:

> Notwithstanding subsection (a)~~(2)~~ or (b)~~(2)~~, where a warning **or hazard statement or other informational statement regarding carcinogenicity or reproductive toxicity** for a consumer product exposure or occupational exposure from use of a pesticide is provided on a product label, and the pesticide label is regulated **and approved** by the United States Environmental Protection Agency under the Federal Insecticide, Fungicide, and Rodenticide Act **and its implementing regulations at** Title 40 Code of Federal regulations, Part 156, **a reference to the information on cancer or reproductive toxicity endpoints contained in the Agency's health assessment for a pesticide and available on the Agency's website shall be deemed clear and reasonable for the purposes of this article.** ~~word "ATTENTION" or "NOTICE" in capital letters and bod type may be substituted for the word "WARNING."~~

C. The Proposed Amendments could be revised to allow reference on a label to information on the SDS to be "clear and reasonable" for purposes of Proposition 65.

This suggestion follows from the discussion in Section II above, describing the determinations by US EPA and OSHA, that the FIFRA labeling and warning requirements conflict with Hazard Communication Standard requirements for SDS under the GHS. We suggest the following language, borrowed from PR Notice 2012-01, and modified for use with Proposition 65:

> This chemical is a pesticide product registered by the United States Environmental Protection Agency and is subject to certain labeling requirements under federal pesticide law. **The product contains certain chemicals "listed" by the State as carcinogens or reproductive toxicants under the California law known as the Safe Drinking Water & Toxic Enforcement Act of 1986 or "Proposition 65."** **Proposition 65 warning information appears below.** ~~These requirements differ from the classification criteria and hazard information required for safety data sheets (SDS), and for workplace labels of non-pesticide chemicals.~~ Health assessment information on cancer and reproductive toxicity is available online on the US EPA website. Hazard information required on the pesticide label under federal law appears on the label, **along with** ~~. is reproduced below. The pesticide label also includes~~ other important information, including directions for use.

This proposal also would resolve a conflict for federal pesticide registrants. Compliance with the Occupational Safety and Health Act and the federal or state Hazard Communication Standard or Worker Protection Standard should satisfy Proposition 65.

IV. REQUEST FOR EXTENSION OF EFFECTIVE DATE

As noted above, the regulations that OEHHA is proposing to amend will take effect on August 30, 2018. It is clear from the discussion above, and from the fact that OEHHA has proposed to amend Section 25603 in its application to exposures from consumer products that are regulated as pesticides, that there is considerable confusion as to how this regulation should be applied to such products. We indicated at n. 19 above that the process for amending labels to include warnings that would be required under Proposition 65 (assuming US EPA will approve them) may take several months at the federal level, and then an additional six months to a year at the state level. Many registrants that have applied for such amendments have been informed that US EPA will not approve their applications. Also, many registrants are facing uncertainty as to what Proposition 65 requires of them, and whether they should continue to attempt to include Proposition 65-like statements on their labels or labeling, or simply rely on their US EPA approved labels as compliant.

For these reasons, it would be fundamentally unfair to leave registrants on the horns of a dilemma as August 30 approaches. We therefore suggest an extension of the effective date of Section 25603 in its application to pesticides registered pursuant to FIFRA, until August 30, 2019. To be clear, we believe that such an extension is appropriate whether or not the Proposed Amendments are adopted.

There is too much uncertainty at this time to allow producers, distributors and retailers to manage their supply chains to manage for compliance.

V. CONCLUSION

CLA, RISE, HCPA and CPDA appreciate OEHHA's attempt to resolve the conflicts between the FIFRA label-warning system and the Proposition 65 warning requirements. However, as we have made clear, we do not support the proposal in its present form. The Proposed Amendments will address only an ancillary issue and will leave those who enforce Proposition 65 with the false impression that the label warnings may be used consistently with both federal and state law, when in fact they cannot. Further, the Proposed Amendments will make the safe harbor warning mandatory in all cases where a product contains a Proposition 65 listed chemical, whether the level of exposure to that chemical would require a warning or not, even though use of the safe harbor warning will be inconsistent with federal law.

CLA, RISE, HCPA and CPDA believe that the alternatives proposed above would effectively resolve this conflict. We would be pleased to participate in further dialogue with the agency regarding these proposals. If OEHHA does not accept these suggestions, we strongly encourage OEHHA to consult with US EPA and to seek input from interested stakeholders before proposing or implementing new safe harbor language.

Respectfully submitted,

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