Final Statement of Reasons

Title 27, California Code of Regulations

Amendments to Article 6
Clear and Reasonable Warnings

Amendment to Section 25603
Consumer Product Exposure Warnings – Content:
Signal Words for
FIFRA-Regulated Pesticide Exposure Warning Labels

December 2018

California Environmental Protection Agency
Office of Environmental Health Hazard Assessment

SUMMARY

The Office of Environmental Health Hazard Assessment (OEHHA) published the Notice for this action on April 27, 2018. The 45-day comment period was scheduled to close on June 11, 2018, but was extended to July 5, 2018 in response to a request from the American Chemistry Council, which also requested a public hearing on the proposal. OEHHA held the public hearing on June 21, 2018. OEHHA received three comments from:

- American Chemistry Council
- Western Plant Health Association
- Combined comments from CropLife America, Responsible Industry for a Sound Environment, Household & Commercial Products Association and Council of Producers & Distributors of Agrotechnology (collectively referred to as CropLife *et al.*).

The same three commenters provided oral comments at the public hearing.

UPDATE OF INITIAL STATEMENT OF REASONS

An update of the Initial Statement of Reasons (ISOR) is not necessary because no changes from the originally proposed amendments have been made.

PUBLIC COMMENTS

A summary of the oral and written comments received on the proposed regulation, along with OEHHA's responses, are provided below.

American Chemistry Council (ACC):

Comment 1: ACC agrees that the current safe harbor regulations for consumer products conflicts with US Environmental Protection Agency (US EPA) Federal Fungicide, Insecticide, and Rodenticide Act (FIFRA) requirements for pesticide labeling, but this proposal does not resolve the conflict. Instead, it introduces new problems. Safe harbor availability is inappropriately contingent upon a third party (US EPA) that OEHHA cannot control.

Response 1: FIFRA is a separate and distinct law from Proposition 65[1], with different requirements. OEHHA does not agree with the commenter that there is a direct conflict between Proposition 65 and FIFRA. In fact, the US Environmental Protection Agency (US EPA) has provided guidance instructing pesticide registration applicants to use the signal words "Attention" or "Notice" in lieu of the word "Warning" to provide a

[1] The Safe Drinking Water and Toxics Enforcement Act of 1986, codified at Health and Safety Code section 25249.5 *et seq*, hereafter referred to as "Proposition 65" or "the Act".

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Proposition 65 warning, and has approved pesticide labels that contain Proposition 65 warnings. OEHHA cannot provide assurances that US EPA will always approve an application based on the use of a given Proposition 65 safe harbor warning on the label. The unavailability of one warning method does not preclude a business from using a different safe harbor warning method. The alternative signal words are just one option that businesses can use to provide a warning under the Act. No changes were made based on this comment.

Comment 2: Pesticide products are like prescription drugs that are also subject to a complex federal program and require a federal agency to approve the specific label for the regulated product before it enters commerce. OEHHA has a safe harbor regulation that accepts otherwise federally compliant labels for a prescription drug as clear and reasonable (See Section 25607.7). ACC encourages OEHHA to adopt a consistent and conceptually identical approach for FIFRA-regulated pesticide products. Proposed alternative language:

> "§ 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."

Response 2: The commenter is correct that Section 25607.7 provides that federally compliant prescription drug labeling, in conjunction with the prescriber's practice of obtaining informed consent from a patient, serves as a safe harbor warning. However, given the significant differences between prescription drugs and pesticides, a warning that is clear and reasonable for a prescription drug is not necessarily clear and reasonable for a pesticide product. An individual uses prescription drugs because a medical professional has determined that the drug's benefits for that individual outweigh the risks. Medical professionals are required to discuss possible drug-related risks with the patient. In contrast, pesticides are poisons that are specifically formulated to kill pests and may be hazardous to consumers who do not use them properly. More importantly, consumers can purchase over-the-counter pesticides without receiving any advice or consultation from a professional. There is no mechanism to ensure that FIFRA-approved labeling will provide a clear and reasonable warning for purposes of Proposition 65. The commenter has provided no support for the suggestion that a person will receive an adequate Proposition 65 warning via a US EPA process that is based on different laws, regulations, goals and purposes than Proposition 65. The proposed alternative language is beyond the scope of the current rulemaking that is only proposing a narrow amendment to the regulations that would allow use of

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alternative signal words for on-product labels approved by US EPA under FIFRA. It is not clear that a separate warning provision is needed for pesticide products. No changes were made based on this comment.

Comment 3: The yellow triangle symbol is not consistent with FIFRA labeling requirements. FIFRA regulations do not allow pictograms and US EPA has prohibited pictograms on approved labels. It is not sufficient to simply delete the symbol.

Response 3: The commenter states that US EPA regulations and guidance "do not allow" the use of a pictogram, but does not point to any specific statutory or regulatory provisions that would preclude the use of a pictogram on a pesticide label. Further, US EPA has not indicated that a pictogram would be precluded under FIFRA. No changes were made based on this comment.

Comment 4: The signal word "WARNING" in FIFRA-approved labels has a specific meaning related to acute health effects and US EPA does not approve the use of the signal word outside of the context of FIFRA. Merely substituting "warning" with a different word in the warning regulations does not address the fundamental basis for the conflict between this proposal and FIFRA.

Response 4: The signal words "NOTICE" or "ATTENTION" do not conflict with any FIFRA requirements that OEHHA is aware of, and the commenter does not provide any support for their contention. The use of the words “NOTICE” or “ATTENTION” as appropriate will allow for Proposition 65 warnings to be consistent with FIFRA requirements. No changes were made based on this comment.

Comment 5: US EPA has clearly stated that the "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." Therefore, adding a Proposition 65 warning to a product otherwise approved under FIFRA could be considered misleading. There is no reasonable certainty that US EPA can or would approve the inclusion of a Proposition 65 warning statement on a pesticide label in any particular case. The proposed regulation cannot deliver the certainty needed to offer viable compliance. OEHHA cannot reasonably predict that any Proposition 65 warning will be approved on a FIFRA label. A safe harbor regulation cannot be contingent on uncertain and future conditions. ACC encourages OEHHA, if it has not already done so, to discuss these matters with US EPA, as US EPA would then need to amend its own regulatory requirements.

Response 5: US EPA guidance provides that pesticide registrants should use the signal words "NOTICE" or "ATTENTION" for Proposition 65 label warnings.[2] OEHHA

[2] See the US EPA Label Review Manual (https://www.epa.gov/sites/production/files/2017-09/documents/lrm-complete-aug-2017.pdf, p. 7-3) :

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cannot compel US EPA to approve such labels, but is providing the option so that pesticide registrants can request US EPA approval for an on-product warning that would meet safe harbor requirements. If US EPA does not approve a label warning, other safe harbor warning methods are available. OEHHA has consulted with US EPA staff regarding this regulatory proposal. No changes were made based on this comment.

Western Plant Health Association (WPHA):

Comment 6: WPHA supports the proposed rulemaking. The proposed amendment provides an option for pesticide registrants to use in modifying the safe harbor content for on-product warnings for pesticide products. It will assist pesticide registrants to comply with Proposition 65 by providing optional language for product warnings for pesticides that are consistent with FIFRA and with the approval of US EPA and related California laws. As further justification for support of the amendment, retail stores have informed WPHA members they will not offer the option of shelf warnings in the marketplace.

Response 6: The intent of the proposed regulation is to provide businesses with a viable method of providing a warning label on pesticide products. Under Section 25600.2, retail sellers are required to pass on warnings received by manufacturers, producers, packagers, importers, suppliers, or distributors. OEHHA does, however, recognize that there may be practical issues between businesses such as those noted by the commenter. The proposed regulation may facilitate the provision of pesticide warnings to the consumer. As OEHHA noted in the ISOR for this rulemaking,

> "Providing warnings on product labels is considered an important safe harbor option because it is more likely to be clearly associated with the exposure for which the warning is being provided. A warning provided on a label is less likely to be lost or separated from the product, as might occur with shelf signs or display signs. In addition, it is more likely that a person being exposed to a listed chemical in a pesticide will see the warning prior to each use of the product if it is placed on the product label, thus furthering the "right-to-know" purposes of the statute" (ISOR, p. 7).

Comment 7: US EPA has not allowed use of an added non-FIFRA related "Warning" on pesticide labels because the signal word has a specific meaning related to potential acute harm to pesticide workers/applicators.

"4. Related Information. Because of the potential for confusion, the Agency historically has not approved labels containing the terms "caution", "warning", or "danger", except as the Signal Word for that label (e.g., "CAUTION: Wash hands before eating, or smoking" on a label with the signal of "Caution"). If the Prop 65 term conflicts with the EPA signal word, then registrants should use "Notice" or "Attention" for the Prop 65 statement so that it does not conflict with the EPA signal word. . However, registrants should use the term "notice" or "attention" instead, so that it does not conflict with the EPA required Signal Word."

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Response 7: Comment noted, no response required.

Comment 8: US EPA does not allow pictograms, so WPHA requests the yellow triangle pictogram be deleted as a requirement for packaged goods. However, the pictogram can be used by retailers and applicator companies within their facilities/sites for occupational and environmental warnings and training programs.

Response 8: Neither US EPA nor the California Department of Pesticide Regulation (DPR) has indicated there is any concern with use of the pictogram for Proposition 65 warnings. OEHHA agrees that the pictogram should also be used on off-product warnings. No changes were made based on this comment.

Comment 9: WPHA wishes to reaffirm that a business may still choose not to take advantage of the safe harbor provisions and provide an otherwise "clear and reasonable" warning that complies with the Act. The amendment does not shift the burden onto or change requirements for small businesses or farmers.

Response 9: The commenter is correct that a business can choose not to use the safe harbor warning methods and content as long as the warning provided is "clear and reasonable." (See section 25600(f) of the regulations.)

Comment 10: US EPA has already provided training and guidance to their pesticide registration review staff via its EPA Label Review Manual, Chapter 7: Precautionary Statements, page 7-3, Item 4. Related Information that states, "California's Proposition 65 may require the term "warning" be used on a label. However, registrants should use the term "notice" or "attention" instead, so that it does not conflict with the EPA required Signal Word."

Response 10: OEHHA agrees with the commenter. No further response is required.

Comment 11: WPHA has been working with US EPA, the Department of Pesticide Regulation (DPR) and OEHHA to complete this warning alternative in time for the August 30, 2018 implementation date. Due to delays at US EPA, alternative warnings are unresolved, and therefore, WPHA asks for a 6-month delay in implementation of any new Proposition 65 warning requirements for consumer-packaged goods regulated under FIFRA from the date of US EPA's decision to approve or not approve the alternative label warning language.

Response 11: Until US EPA decides on individual applications for on-label warnings, businesses can provide warnings using the other safe harbor warning methods and content in Subarticle 2, or they may provide their own non-safe harbor warnings that are consistent with the Act. No changes were made based on this comment.

Comment 12: The best-case scenario would be to have a single streamline label without the need for arbitration between agencies. In lieu of that future ideal, this proposal achieves a reasonable fix to the predicament.

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Response 12: Comment noted, no response required.

CropLife America, Responsible Industry for a Sound Environment, Household & Commercial Products Association and Council of Producers & Distributors of Agrotechnology (CropLife *et al.*):

Comment 13: CropLife *et al.* agrees that the current safe harbor regulations for consumer products conflicts with US EPA FIFRA requirements for pesticide labeling, but the proposal does not resolve the conflict. The proposed amendments frame the conflict too narrowly and do not address the fundamental underlying issues: (1) the different purposes of the warnings under the two schemes and criteria for deciding when such warnings are required; and (2) the primacy of FIFRA requirements which fosters uniformity in warnings throughout the US and relieve interstate producers from duplicative burdens to obtain multiple approvals from state and federal agencies.

Response 13: OEHHA disagrees that the safe harbor regulations for consumer products generally conflict with US EPA FIFRA requirements. This proposed amendment would provide a narrow exception to the signal word requirement for the safe harbor warning content available for on-product warnings for exposures to listed chemicals in pesticide products. The commenter is correct that FIFRA and the Act are separate laws, with different requirements. The signal word amendments are intended to harmonize with the labeling requirements of FIFRA to allow a business the option of providing a Proposition 65 safe harbor warning on the product label that is determined to be "clear and reasonable" for purposes of Proposition 65. US EPA has approved Proposition 65 warnings for pesticide labels in the past and US EPA will make its own determinations concerning pending and future applications for labels that include a Proposition 65 warning. No changes were made based on this comment.

Comment 14: OEHHA could achieve its objective by amending the regulations to provide that: (1) US EPA approved labels for pesticide products would be deemed to comply with Proposition 65; (2) reference to US EPA risk assessments for Proposition 65 toxicity endpoints would satisfy Proposition 65; or (3) US EPA approved labels in combination with warnings on Safety Data Sheets (SDS) that comply with federal or state Hazard Communication Standard or the Worker Protection Standard for pesticides satisfy Proposition 65.

Response 14: The amendments to the safe harbor warnings for consumer product pesticide exposures is intended to provide a narrow exception to the signal word requirements for on-product labels for FIFRA-regulated products. The commenter is requesting changes to the regulations that would go well beyond the existing proposal. Further, Section 25606 of the regulations allows a business to satisfy the Proposition 65 warning requirements for occupational exposures if it fully complies with all warning,

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information, training, and labeling requirements under the federal HCS, California HCS, or California Pesticides and Worker Safety requirements. There is no need to amend the regulations further in order to incorporate OSHA requirements for occupational exposures to listed chemicals.

Comment 15: Proposition 65 is intended to provide information regarding potential hazards whether risks are present. The FIFRA label warning system is designed to communicate information to mitigate risks. To view the conflict as an inconsistency regarding signal word use ignores the federal pesticide labeling law. The fundamental conflict is far more important than divergent signal word use.

Response 15: OEHHA disagrees with the commenter that the two laws conflict with each other. US EPA has approved the inclusion of Proposition 65 warnings on pesticide labels. The current proposal simply allows the use of alternative signal words for on-product labels for FIFRA-regulated pesticide products. Other warning options are available in the event US EPA does not approve a given label application.

Comment 16: Exposure levels permitted under FIFRA are significantly less than the exposure levels for which a warning is required under Proposition 65. US EPA's decision to register a pesticide product is tantamount to a determination that exposure to 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. Thus, a Proposition 65 warning on an US EPA approved FIFRA label implicitly contradicts the use instructions, precautionary statements and the registration itself.

Response 16: The commenter has not provided any support for its contention that FIFRA registration requirements will always ensure that exposure to a listed chemical in a given pesticide product will be below the warning threshold for Proposition 65. Whether or not a Proposition 65 warning is consistent with other US EPA requirements is a decision that is best left to US EPA. The current rulemaking proposal simply provides a narrow exception to the signal word requirement for FIFRA-regulated products that a business can use in its label application.

Comment 17: Because Proposition 65 places the burden on the business to prove that the exposure level has not been exceeded or that the warning provided is clear and reasonable, the proposed safe harbor label warning will become mandatory. Federal registrants will be compelled to use it because it will be the only warning that will avoid Proposition 65 litigation.

Response 17: The commenter is incorrect that a safe harbor warning using the proposed signal words would be the only way for a business to provide a compliant Proposition 65 warning. A business could provide the warning using any one of four methods for a consumer product exposure warning in Section 25602 or for occupational

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exposure warnings could provide a warning consistent with the federal or California HCS or California Pesticides and Worker Safety requirements. Further, the safe harbor warning regulations are not mandatory. They are guidance for businesses on how to provide a warning that is deemed to be "clear and reasonable" for purposes of Proposition 65. A business may choose to use a different warning method or content as long as it meets the "clear and reasonable" requirement of the Act.

Comment 18: US EPA does not permit Globally Harmonized System (GHS) statements and pictograms for pesticide product classification and labeling. To address the conflict between the required pictogram use under GHS and the lack of a pictogram in the FIFRA labeling requirements, US EPA urged federal registrants to include FIFRA labeling information in the Safety Data Sheets (SDS).

Response 18: The warning symbol prescribed in the safe harbor warning for consumer products is not a GHS pictogram. During the development of the regulatory proposal for the Article 6 Clear and Reasonable Warnings regulations, a GHS pictogram was initially considered but later rejected. The current familiar triangle with an exclamation point was adopted instead. OEHHA is not aware of any actual conflict between use of the symbol and US EPA FIFRA requirements.

Comment 19: No other state attempts to compel registrants to include state-specific warnings on their US EPA approved labeling. The proposed amendment will compel registrants to do so and will serve as precedent for other states to follow. The FIFRA label warning system cannot tolerate competing state requirements because it would create confusion and be a burden on US EPA.

Response 19: The proposed amendment does not compel additional warnings or warnings on product labels. Rather, the amendment would provide optional signal words that businesses could use to provide safe harbor warnings for pesticide products regulated under FIFRA. US EPA will decide whether to approve including a Proposition 65 warning in a given label application.

Comment 20: Historically, US EPA has denied applications to include Proposition 65 statements on FIFRA labels. US EPA regulations, not OEHHA regulations, remain the authority for determining what information will appear on a FIFRA label.

Response 20: OEHHA disagrees with the comment. US EPA has approved Proposition 65 warnings on product labels in some circumstances. The proposed amendment is consistent with current US EPA guidance for providing Proposition 65 warnings on pesticide labels regulated under FIFRA. The commenter is correct that on-product labeling for pesticides regulated under FIFRA would need to be approved by US EPA. No changes were made based on this comment.

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Comment 21: The new safe harbor regulations have already taken into account several fundamental principles for other specific product types that ought to be applied to a pesticide specific regulation. OEHHA has established these new regulations for other products, so it would not be burdensome for OEHHA to craft a similar regulation for pesticide products.

Response 21: The commenter is asking for a regulatory action that is far beyond the scope of the current rulemaking proposal. The current proposal is a narrow exception to the consumer product warning provisions that modifies the acceptable signal word requirement for labels on FIFRA-regulated products. OEHHA will monitor the situation and consider whether additional regulatory action is needed in the event issues arise in the future. No changes were made based on this comment.

Comment 22: Safe harbor warning for pesticides should be well-grounded within FIFRA, so that federal registrants can be assured that it will be approved by US EPA and not questioned by DPR or any other state or territory in the US.

Response 22: The proposed amendment would provide businesses with the option to use alternative signal words for on-product labels for FIFRA-regulated products. It is up to US EPA to decide in any given case whether a label application will be approved. In the past, US EPA has allowed on-product Proposition 65 warnings for FIFRA-regulated pesticides.

Comment 23: The proposed amendments are flawed because the US EPA policy change that is contemplated would require US EPA to amend existing FIFRA regulations through federal rulemaking.

Response 23: The proposed exception allowing alternative signal words for on-product labels for FIFRA-regulated pesticides is consistent with US EPA guidance for businesses requesting label approval. OEHHA is not requiring US EPA to take any action by adopting these minor regulatory changes. No changes were made based on this comment.

Comment 24: A safe harbor regulation should be self-effectuating. A federal registrant should not need to ask US EPA permission to add a state warning or be dependent on US EPA's discretion to approve. 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 subject to a delay in registration while US EPA and DPR review a request for product label amendment.

Response 24: This comment is beyond the scope of the proposed rulemaking. The proposed amendment would provide businesses with the option to propose a Proposition 65 warning for a FIFRA-regulated pesticide product label. Other options for

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providing safe harbor warnings are available to registrants if they prefer to use them. OEHHA defers to DPR and US EPA regarding their registration processes.

Comment 25: The safe harbor for US EPA-regulated pesticides could follow the model and language of safe harbor for prescription drugs. CropLife *et al.* suggests:

> "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."

Response 25: The commenter is correct that Section 25607.7 provides that federally compliant prescription drug labeling, in conjunction with the prescriber's practice of obtaining informed consent from a patient, serves as a safe harbor warning. However, given the significant differences between prescription drugs and pesticides, a warning that is clear and reasonable for a prescription drug is not necessarily clear and reasonable for a pesticide product. An individual uses prescription drugs because a medical professional has determined that the drug's benefits for that individual outweigh the risks. Medical professionals are required to discuss possible drug-related risks with the patient. In contrast, pesticides are poisons that are specifically formulated to kill pests and may be hazardous to consumers who do not use them properly. More importantly, consumers can purchase over-the-counter pesticides without receiving any advice or consultation from a professional. There is no mechanism to ensure that FIFRA-approved labeling will provide a consumer with a clear and reasonable warning for purposes of Proposition 65. The commenter has provided no support for the idea that a person will receive an adequate Proposition 65 warning via a US EPA process that is based on different laws, regulations, goals and purposes than Proposition 65. The proposed alternative language is beyond the scope of the current rulemaking that is only proposing a narrow amendment to the regulations that would allow use of alternative signal words for on-product labels approved by US EPA under FIFRA. It is not clear that a separate warning provision is needed for pesticide products. No changes were made based on this comment.

Comment 26: 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. CropLife *et al.* suggests:

> "§ 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."

Response 26: There is case law establishing that an invitation to inquire about possible warnings on products is not equivalent to providing the consumer a warning about a product.[3] A business that wishes to include references to such information as a useful adjunct to a warning is free to do so. The suggested new regulatory provision is well beyond the scope of the current rulemaking. OEHHA's safe harbor warning regulations are not mandatory. A business is free to use an alternative warning method and content but would need to be prepared to defend it as "clear and reasonable" in any subsequent enforcement action. No changes were made based on this comment.

Comment 27: Another proposed alternative to the proposed amendments would change the proposal to 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. CropLife *et al.* suggests the additions indicated in underline below:

> "Notwithstanding subsection (a)(2) or (b)(2), where a warning <u>or hazard statement or other informational statement regarding carcinogenicity or reproductive toxicity</u> 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 <u>and approved</u> by the United States Environmental Protection Agency under the Federal Insecticide, Fungicide, and Rodenticide Act <u>and its implementing regulations at</u> Title 40 Code of Federal regulations, Part 156, <u>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."</u>

Response 27: As discussed in the response to the previous comment, the commenters' proposal runs counter to case law establishing that a Proposition 65 consumer product warning must be provided directly to the consumer, and that information that a consumer must seek out is not considered a warning. Further, US EPA health assessments are by their nature scientific documents that are written primarily for

[3] *Ingredient Communication Council (ICC) v. Lungren* (1992) 2 Cal. App. 4th 1480

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scientists and scientifically literate policymakers. While a motivated layperson might glean useful information from reading a US EPA assessment, it is unrealistic to expect that most users of pesticide products would attempt to read a highly scientific document or that they would find the technical information in such documents to be clear or reasonable.

These suggestions are beyond the scope of the rulemaking, which only proposed a minor amendment to the regulations that would allow alternative signal words on certain pesticide product labels. OEHHA's safe harbor warning regulations are not mandatory. A business is free to use an alternative warning method and content but would need to be prepared to defend it as "clear and reasonable" in any subsequent enforcement action. No changes were made to the proposed amendment based on this comment.

Comment 28: 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. It would resolve compliance with OSHA and federal and state Hazard Communication Standard or Worker Protection Standard. CropLife *et al.* suggests borrowing language from Pesticide Regulation Notice 2012-1 [USEPA-OPP, Material Safety Data Sheets as Pesticide Labeling]:

> "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. 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 other important information, including directions for use."

Response 28: This suggestion is beyond the scope of the proposed rulemaking. It requests that OEHHA adopt a warning method for pesticides that is based on certain OSHA-related requirements for occupational exposures. This proposal would not be acceptable for a consumer product warning. As stated in the previous two responses, case law has established that a Proposition 65 warning must be provided directly to the consumer, and that information that an individual must seek out is not a warning. OEHHA's safe harbor warning regulations are not mandatory. A business is free to use an alternative warning method and content but would need to be prepared to defend it as "clear and reasonable" in any subsequent enforcement action. No changes were made based on this comment.

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Comment 29: There is considerable confusion as to how this regulation should be applied to pesticide products. The process for amending labels to include warnings 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. CropLife *et al.* suggests an extension of the effective date of Section 25603 in its application to pesticides registered pursuant to FIFRA, until August 30, 2019. Such an extension is appropriate whether or not the proposed amendments are adopted.

Response 29: The new Proposition 65 warning regulations do not require a warning for any product, nor have they changed the criteria that trigger the need for a warning. The regulations apply only where a business has determined a warning is needed and the business wishes to take advantage of the safe harbor protection provided by the regulation. The regulations include other methods for providing the warning in addition to product labels. A business may provide a warning using any method or content it chooses as long as the resulting warning is "clear and reasonable" as required by the statute. No extension of the effective date of the regulations is needed to address this issue. No changes were made based on this comment.

Comment 30: 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. Also, it will make safe harbor mandatory in all cases where a product contains a Proposition 65 listed chemical, whether the exposure level to that chemical would require a warning or not, even though use of the safe harbor warning will be inconsistent with federal law.

Response 30: OEHHA disagrees that the narrow exception to the signal words that may be used for safe harbor warning content is inconsistent with FIFRA, and is unaware of any conflict with state law. Additionally, the safe harbor warning regulations contain other options for providing safe harbor warnings, and safe harbor warnings are not mandatory. They are guidance for businesses on how to provide a warning that is deemed to be "clear and reasonable" for purposes of Proposition 65. A business is free to use an alternative warning method and content but would need to be prepared to defend it as “clear and reasonable” in any subsequent enforcement action. No changes were made based on this comment.

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Comment 31: If OEHHA does not accept these suggestions, CropLife *et al.* strongly encourages OEHHA to consult with US EPA and seek input from interested stakeholders before proposing or implementing new safe harbor language.

Response 31: OEHHA has consulted with US EPA staff on this proposal. The public comment period and public hearing provided interested stakeholders with a full opportunity to give input on this proposal. As reflected in the previous responses, OEHHA carefully considered the input from US EPA, DPR and the public throughout this rulemaking process. No changes were made to the proposed amendments based on this comment.

ALTERNATIVES DETERMINATION

In accordance with Government Code section 11346.9(a)(7), OEHHA has considered available alternatives to determine whether any alternative would be more effective in carrying out the purpose for which the regulations were proposed. OEHHA has also considered whether an alternative existed that would be as effective as, and less burdensome to affected private persons than, the proposed action. OEHHA has determined that no alternative considered would be more cost-effective, or as effective in implementing the statutory policy or other provision of law. The various alternatives to the addition of subsection (d) to Section 25603 were considered and are discussed in the responses to comments. Another alternative would be to not amend the regulation to specifically address the use of an alternative signal word for exposure warnings for pesticides listed under Proposition 65. This is not a reasonable alternative because pesticide registrants may be unable to comply with both the state warning requirement and the federal labeling requirement as it relates to exposures from pesticides listed under Proposition 65. Without the proposed amendments, businesses, pesticide registrants in particular, may not be able to use a warning on a pesticide label to provide a Proposition 65 warning. This regulation furthers the “right-to-know” purposes of the statute and provides more specificity regarding alternate safe harbor warnings content for exposures to listed pesticides.

LOCAL MANDATE DETERMINATION

OEHHA has determined this regulatory action will not impose a mandate on local agencies or school districts nor does it require reimbursement by the State pursuant to Part 7 (commencing with Section 17500) of Division 4 of the Government Code. Local agencies and school districts are exempt from Proposition 65. OEHHA has also determined that no nondiscretionary costs or savings to local agencies or school districts will result from this regulatory action.

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