

**Initial Statement of Reasons
Title 27, California Code of Regulations
Proposed 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**

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**California Environmental Protection Agency
Office of Environmental Health Hazard Assessment**

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SUMMARY

Proposition 65¹ requires that businesses give a “clear and reasonable” warning to individuals before knowingly and intentionally exposing them to a chemical listed as known to cause cancer or reproductive toxicity. The Office of Environmental Health Hazard Assessment (OEHHA) is the lead agency that implements Proposition 65. OEHHA maintains the list of chemicals known to the state to cause cancer or reproductive toxicity and has the authority to promulgate and amend regulations to further the purposes of the Act.² On August 30, 2016, OEHHA adopted a new set of Article 6 Clear and Reasonable Warnings regulations (Title 27, Cal. Code of Regs., section 25600 *et seq.*)³ intended to make Proposition 65 warnings more informative and meaningful than the previous Article 6 regulations adopted by OEHHA’s predecessor entity in 1988. The new Article 6 regulations become effective on August 30, 2018, at which time the older Article 6 regulations will no longer be operative and will be repealed. The new Article 6 regulations include additional guidance concerning safe harbor⁴ warning content for consumer product exposure warnings.”⁵

This proposed rulemaking would add a new subsection (d) to Section 25603, addressing safe harbor warning content for on product labels for consumer product and occupational exposures⁶ to listed chemicals from the use of pesticides where those labels are regulated under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)⁷ and related California laws and regulations.⁸ This new subsection would further the “right-to-know” purposes of the statute and clarify the content of safe harbor warnings for exposures that can occur from the use of pesticide products, where those warnings are provided on

¹ Health and Safety Code Section 25249.5 *et seq.*, The Safe Drinking Water and Toxic Enforcement Act of 1986, commonly known as “Proposition 65”. Hereafter referred to as “Proposition 65” or “the Act”.

² Health and Safety Code Section 25249.12(a)

³ All further references are to Title 27 of the California Code of Regulations, unless otherwise indicated.

⁴ The term “safe harbor” is used throughout to refer to non-mandatory guidance provided by OEHHA for the methods and content of warnings the agency has deemed to meet the “clear and reasonable” standard required by the Section 25249.6 of the Act.

⁵ Title 27, Cal. Code of Regs., section 25603.

⁶ Occupational warnings are addressed in Section 25606; subsection (b) of that regulation cross-references to the consumer product exposure warning provisions.

⁷ 40 CFR Part 156

⁸ Food & Agricultural Code sections 12781 and 14005; Title 3, Cal. Code of Regs., sections 6235-6243.

a label that is regulated under FIFRA and certain California laws. This regulation is intended to provide compliance assistance for businesses that cause pesticide exposures in order to reduce the potential for litigation concerning the sufficiency of warnings, while still allowing them to comply with other federal and state requirements for warnings provided on a label. The methods and content provided in the regulation are deemed “clear and reasonable” by the lead agency for purposes of the Act.

BACKGROUND

Except in limited circumstances,⁹ pesticides¹⁰ sold or distributed in the United States must be registered by the United States Environmental Protection Agency (US EPA) under FIFRA.¹¹ As part of the review and approval process, US EPA evaluates each pesticide label to ensure directions of use and safety measures are appropriate for any potential risk.¹² All label language must be approved by US EPA before a pesticide can be sold or distributed in the United States. As such, the pesticide label is considered an enforceable document under FIFRA. Each pesticide label must use the signal word reflecting the Toxicity Category (Category I being the highest category and Category IV being the lowest) to which the product is assigned by US EPA.¹³ The signal words used under FIFRA include “Danger” (Toxicity Category I), “Warning” (Toxicity Category II), and “Caution” (Toxicity Categories III and IV).¹⁴ In addition, pesticides must be registered by the California Department of Pesticide Regulation (DPR) before they can be sold or offered for sale in California. In addition, DPR has its own statutory and regulatory requirements that address pesticide product labeling.¹⁵

Under the Proposition 65 regulations, safe harbor warnings are required to include the signal word, “**WARNING**” within the warning content of the message. To avoid confusion caused by conflicting signal words on a label, US EPA historically has not approved labels containing the terms “caution”, “warning”, or “danger”, unless the word is the same as the US EPA-required signal word for

⁹ 40 CFR § 152.25

¹⁰ As defined in 7 U.S.C. § 136(u).

¹¹ 40 CFR Part 156

¹² About Pesticide Registration, EPA (2017) <https://www.epa.gov/pesticide-registration/about-pesticide-registration> (last visited Mar 26, 2018).

¹³ 40 CFR § 156.64

¹⁴ *Id.*

¹⁵ Food & Agricultural Code Sections 12781, 14005 and Title 3, Cal. Code of Regs., sections 6235-6243.

that label.¹⁶ US EPA recommends that if a Proposition 65 signal word conflicts with the US EPA-required signal word, then a registrant should instead use "Notice" or "Attention" for the Proposition 65 warning so that it does not conflict with the US EPA-required signal word.¹⁷

This means that 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 if the Toxicity Category signal word required under FIFRA is a word other than "**WARNING**".¹⁸ In the case of those pesticides registered for use by US EPA (and DPR) that carry a signal word other than "**WARNING**" on their approved labels, the affected businesses (pesticide registrants) are therefore limited in the methods and content of the warning they can provide under Proposition 65, compared to other businesses not regulated under FIFRA or the California Food and Agricultural Code¹⁹ and its implementing regulations.²⁰

In proposing this regulatory action, OEHHA intends to provide a narrow exception to the safe harbor provisions as they relate to the content of pesticide exposure warnings on product labels. OEHHA is only allowing use of an alternate signal word in the narrow circumstance where the US EPA and DPR signal word and the Proposition 65 signal word conflict. This regulatory amendment will help businesses provide information that is useful to Californians about their potential exposures to listed pesticides and provide more guidance to affected businesses, thereby furthering the purposes of the Act. The proposed amendment to the warning regulations is discussed below.

§ 25603(d) Consumer Product Exposure Warnings – Content

OEHHA is proposing to add a new subsection (d) to the consumer product exposure warning content set forth in Section 25603. Proposed subsection (d) would allow a business to provide an alternate signal word on a product label for exposures to listed chemicals from a pesticide where the label is regulated under FIFRA and California law. Specifically, the alternate signal words, "**ATTENTION**" or "**NOTICE**" in capital letters and bold print may be used instead of the word "**WARNING**" when the pesticide label is regulated by US EPA pursuant to FIFRA

¹⁶ Label Review Manual, EPA p. 7-3 (2017), available at <https://www.epa.gov/sites/production/files/2017-09/documents/lrm-complete-aug-2017.pdf> (last accessed Mar 26, 2018).

¹⁷ *Id.*

¹⁸ 40 CFR §156.64(b).

¹⁹ Food & Agricultural Code sections 12781 and 14005.

²⁰ Title 3, Cal. Code of Regs., sections 6235-6243.

and DPR under the Food and Agricultural Code²¹ and its implementing regulations.²² This exception only applies where US EPA or DPR require the use of a signal word other than “**WARNING**”. OEHHA believes that in these limited circumstances, the use of the alternative signal words “**ATTENTION**” or “**NOTICE**” will bring attention to the warning without interfering with the US EPA or DPR labeling requirements.

PROBLEMS BEING ADDRESSED BY THIS RULEMAKING

Manufacturers of pesticides wishing to provide a safe harbor warning on the product label for listed chemicals are currently unable to do so if they must use different signal words to meet the requirements of FIFRA or related California laws. This proposed regulatory action is intended to respond to this problem by providing for the use of alternative signal words in safe harbor warnings while still providing meaningful warnings for listed chemical exposures.

NECESSITY

Businesses are precluded under FIFRA from providing the safe harbor warning specified in Subarticle 2 on a label for a pesticide product if FIFRA requires a signal word other than “Warning”. FIFRA prohibits a pesticide from 1) bearing a signal word with a higher toxicity category than indicated by the route of exposure, 2) bearing a signal word with a lower toxicity category than indicated by the route of exposure, and 3) bearing a different signal words on different parts of the label.²³ Therefore, pesticide manufacturers wishing to use the existing safe harbor language may find it conflicts with the signal word required by federal law for pesticides other than those with a "Warning" (Toxicity Category II) signal-word designation by US EPA. An alternative signal word for these pesticides is necessary to allow businesses that manufacture pesticide products requiring “Danger” or “Caution” signal words (Toxicity Categories I, III, or IV under FIFRA) to provide a safe harbor warning directly on the product label if they choose to do so, without running afoul of the FIFRA or DPR labeling requirements. This proposed amendment would provide a narrow exception for businesses that must comply with both the warning requirements of the Act and federal and California law related to labels on pesticide products.

²¹ Food & Agricultural Code Sections 12781, 14005.

²² Title 3, Cal. Code of Regs., sections 6235-6243.

²³ 40 CFR § 156.64

BENEFITS OF THE PROPOSED REGULATION

This proposed regulatory amendment would benefit businesses subject to the Act by providing the option to use an alternative signal word on product labels for safe harbor warnings on pesticide products that are regulated by US EPA and DPR. 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. Providing such information on the product label would also further promote public health and safety. The proposed regulatory amendment would benefit affected businesses by providing a safe harbor alternative that is not currently available that would allow them to comply with the regulation concerning warnings for exposures to listed chemicals in pesticides, while still complying with other federal and state laws. Businesses would also benefit from the added assurance of a safe harbor from potential enforcement actions for product warnings.

TECHNICAL, THEORETICAL, AND/OR EMPIRICAL STUDY, REPORTS, OR DOCUMENTS RELIED UPON

OEHHA did not rely on any technical, theoretical, and/or empirical study, reports, or documents as part of this rulemaking.

REASONABLE ALTERNATIVES TO THE REGULATION AND THE AGENCY’S REASONS FOR REJECTING THOSE ALTERNATIVES

One alternative considered would be not to propose alternative signal words for safe harbor warnings labels for exposures to listed chemicals in pesticides. This alternative would not allow businesses to use signal words other than “**WARNING**” on a label, which could conflict with FIFRA or certain California laws for pesticide labeling. OEHHA is not aware of any other reasonable alternatives to the proposed regulation that would better allow business to provide a safe harbor warning on a pesticide label while complying with other federal and state laws and furthering the purposes of the Act.

REASONABLE ALTERNATIVES TO THE PROPOSED REGULATORY ACTION THAT WOULD LESSEN ANY ADVERSE IMPACT ON SMALL BUSINESS

The proposed amendment will not adversely impact very small businesses because Proposition 65 is limited by its terms to businesses with 10 or more employees.²⁴

EVIDENCE SUPPORTING FINDING OF NO SIGNIFICANT ADVERSE ECONOMIC IMPACT ON ANY BUSINESS

The proposed regulatory action will not have a significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states. The proposed amendment does not impose any new requirements upon private persons or businesses because it provides voluntary safe harbor content for warnings already required under the Act. A business still has the option of providing the warning required by Section 25249.6 of the Act in any manner and with any content it can show is “clear and reasonable” under the law.

EFFORTS TO AVOID UNNECESSARY DUPLICATION OR CONFLICTS WITH FEDERAL REGULATIONS CONTAINED IN THE CODE OF FEDERAL REGULATIONS ADDRESSING THE SAME ISSUES

Proposition 65 is a California law that has no federal counterpart. The statute specifically provides that warnings are only required to the extent they do not conflict with federal law.²⁵ OEHHA has determined that, as drafted, the proposed amendment does not duplicate and will not conflict with federal regulations. This regulatory action will allow safe harbor pesticide warnings to be provided on a product label without conflicting with the signal word requirements of FIFRA and related California laws.

ECONOMIC IMPACT ASSESSMENT

Gov. Code section 11346.3(b)

OEHHA finds there will be no significant economic impact related to this proposed regulatory action. The proposed regulatory amendment would not impose any significant costs because businesses are already subject to the warning requirements of Proposition 65. The proposed amendment does not

²⁴ Health and Safety Code Sections 25249.5, 25249.6, and 25249.11(b)

²⁵ Health and Safety Code Section 25249.10(a) (Exempting warnings governed by federal law.)

impose any mandatory requirements that would significantly increase costs for businesses. The proposed amendment interprets and makes specific the warning requirements of the Act by providing a narrow exception regarding signal words used for warnings on pesticide product labels. 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.

Creation or Elimination of Jobs within the State of California

This proposed regulatory amendment will not impact the creation or elimination of jobs within the State of California. The proposed amendment provides a narrow exception to the signal word requirements under the safe harbor provisions for affected businesses opting to provide safe harbor warnings on product labels for exposures to listed chemicals from the use of pesticides.

Creation of New Businesses or Elimination of Existing Businesses within the State of California

This proposed regulatory action will not impact the creation of new businesses or the elimination of existing businesses within the State of California. The proposed amendment provides a narrow exception for non-mandatory safe harbor warning content for exposures to listed chemicals from the use of pesticides where the warning is provided on a product label that is regulated under FIFRA and related California laws.

Expansion of Businesses Currently Doing Business within the State of California

This proposed amendment will not impact the expansion of businesses within the State of California. The proposed amendment provides a narrow exception for non-mandatory safe harbor warning content for exposures to listed chemicals from the use of pesticides where the warning is provided on a product label that is regulated under FIFRA and related California laws.

Benefits of the Proposed Regulation to the Health and Welfare of California Residents, Worker Safety, and the State’s Environment

The proposed amendment will further the purposes of Proposition 65 by providing more informative warnings to the public and reduce uncertainty for businesses that must comply with the warning requirements of the Act while also complying with FIFRA and other related California laws. The proposed amendment will benefit the health and welfare of California residents by providing more information to the public and facilitating compliance with the Act for

businesses that cause exposures to listed pesticides. The proposed amendments would allow businesses to provide warnings on pesticide labels for occupational exposures to listed pesticides where workers are more likely to see them, thus promoting worker health and safety. The proposed changes may encourage businesses to provide a safe harbor warnings for listed chemicals in pesticides, thus increasing the likelihood that consumers and workers will be aware of the potential hazards of exposures to listed chemicals, which may in turn help consumers make informed decisions about their use of, and exposure to, pesticide products that can pose a risk of cancer, birth defects or other reproductive harm.