

July 29, 2021

PROPOSED REGULATIONS ON SAFE HARBOR WARNING LANGUAGE FOR GLYPHOSATE UNDER CALIFORNIA'S PROPOSITION 65

To Our Clients and Friends:

On July 23, 2021, the California Office of Environmental Health Hazard Assessment (OEHHA) released an Initial Statement of Reasons (ISOR) and proposed text for new regulations concerning safe harbor warnings under California's Safe Drinking Water and Toxics Enforcement Act of 1986 (Proposition 65) for consumer products containing the herbicide, glyphosate. Glyphosate is the active ingredient in Monsanto Company's Roundup, which is used worldwide in agriculture and other applications.

Proposition 65 generally requires consumer products sold in California to bear a warning label if they expose consumers to chemicals listed by the state as causing cancer or reproductive or developmental toxicity. Glyphosate was added to the list of chemicals causing cancer in 2017 based on the International Agency for Research on Cancer (IARC)'s determination that it is a "probable" human carcinogen.[1]

Despite glyphosate's listing as a carcinogen under Proposition 65, the issue of glyphosate's carcinogenicity has proven highly controversial, with major public authorities on carcinogens reaching conflicting conclusions. US EPA, for example, has concluded that glyphosate is "not likely to be carcinogenic to humans." [2] A number of recent high-profile personal injury actions against Monsanto have resulted in massive jury verdicts for plaintiffs who claimed that exposure to glyphosate in Roundup caused their cancers.[3]

Monsanto's legal challenge to glyphosate's addition to the Proposition 65 list was unsuccessful,[4] but, in June 2020, the U.S. District Court for the Eastern District of California issued a permanent injunction against enforcement of Proposition 65 warnings for glyphosate.[5] The court held that the standard safe harbor warning language—including that glyphosate is "known to the State of California to cause cancer"—violated glyphosate sellers' First Amendment rights against compelled speech, because it would force them to take one side of a controversial issue, despite "the great weight of evidence indicating that glyphosate is not known to cause cancer." [6]

The ISOR for the proposed regulations discusses the scientific and legal controversy surrounding glyphosate,[7] which has plainly motivated and shaped the text of the proposed regulations. Indeed, the new warning language proposed for glyphosate appears crafted to avoid the First Amendment problems that gave rise to the preliminary injunction in *Wheat Growers*, though the ISOR notes that the injunction remains in effect, so "no enforcement actions can be taken against businesses who do not provide warnings for significant exposures to [glyphosate]." [8] The ISOR further explains that glyphosate presents "an unusual case because several regulatory agencies did not reach a similar conclusion as IARC," and, therefore, "[t]he standard Proposition 65 safe harbor warning language . . . is not the best fit in this situation." [9]

OEHHA proposes to add section 25607.49 to title 27 of the California Code of Regulations, which would provide:

(a) A warning for exposure to glyphosate from consumer products meets the requirements of this subarticle if it is provided using the methods required in Section 25607.48 and includes the following elements:

(1) The symbol required in Section 25603(a)(1)

(2) The words “**CALIFORNIA PROPOSITION 65 WARNING**” in all capital letters and bold print.

(3) The words, “Using this product can expose you to glyphosate. The International Agency for Research on Cancer classified glyphosate as probably carcinogenic to humans. Other authorities, including USEPA, have determined that glyphosate is unlikely to cause cancer, or that the evidence is inconclusive. A wide variety of factors affect your personal cancer risk, including the level and duration of exposure to the chemical. For more information, including ways to reduce your exposure, go to www.P65Warnings.ca.gov/glyphosate.”

(b) Notwithstanding subsection (a), and pursuant to Section 25603(d), where the warning is provided on the product label, and the label is regulated by the United States Environmental Protection Agency under the Federal Insecticide, Fungicide, and Rodenticide Act, Title 40 Code of Federal Regulations, Part 156; and by the California Department of Pesticide Regulation under Food and Agricultural Code section 14005, and Cal. Code Regs., title 3, section 6242; the word “ATTENTION” or “NOTICE” in capital letters and bold type may be substituted for the words “CALIFORNIA PROPOSITION 65 WARNING.”

Section 25607.48 would also be added to make clear that the warning must be provided using a method listed in Section 25602.

Adoption of these regulations may trigger an effort to alter or lift the *Wheat Growers* injunction, though the district court rejected several alternative warning formulations that are similar to OEHHA’s current proposal.^[10] If the injunction is modified, businesses involved in distribution, sale, or use of glyphosate-containing products in California would not be *required* to use the new warning language, since it is merely a safe harbor, but doing so would be sufficient to avoid violation of Proposition 65’s warning requirement.^[11]

OEHHA’s announcement, the proposed text of the new regulations, and the ISOR are linked below. OEHHA will receive public comments on the proposed regulations until September 7, 2021.:

<https://oehha.ca.gov/proposition-65/crnrr/notice-proposed-rulemaking-warnings-exposures-glyphosate-consumer-products-new>

Regulation text

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Initial Statement of Reasons

[1] <https://oehha.ca.gov/proposition-65/chemicals/glyphosate>

[2] <https://www.epa.gov/ingredients-used-pesticide-products/glyphosate>

[3] *See, e.g., Hardeman v. Monsanto Co.*, No. 16-cv-00525-VC (E.D. Cal. filed Feb. 1, 2016); *Pilliod v. Monsanto Co.*, No. RG17862702, JCCP No. 4953 (Cal. Super. Ct. Alameda Cty. filed Jun 2, 2017).

[4] *Monsanto Co. v. Office of Environmental Health Hazard Assessment*, 22 Cal. App. 5th 534 (2018).

[5] *Nat'l Ass'n of Wheat Growers v. Becerra*, 468 F. Supp. 3d 1247, 1266 (E.D. Cal. 2020) (on appeal to the Ninth Circuit Court of Appeals, Case No. 20-16758).

[6] *Id.* at 1260.

[7] Initial Statement of Reasons, July 23, 2021, at pp. 5-6, 12.

[8] *Id.* at 12.

[9] *Id.* at 6.

[10] *Wheat Growers*, 468 F. Supp. 3d at 1262-63.

[11] Cal. Health & Safety Code § 25249.6



Gibson Dunn's lawyers are available to assist in addressing any questions you may have regarding these developments. Please contact the Gibson Dunn lawyer with whom you usually work, any member of the firm's Environmental Litigation and Mass Tort practice group, or the following authors:

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